MEDICAL DEVICE SAFETY

HEARINGS

BEFORE THE

SUBCOMMITTEE ON
HEALTH AND THE ENVIRONMENT

OF THE

COMMITTEE ON
ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIRST CONGRESS

ON

H.R. 3095

A BILL TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO MAKE IMPROVEMENTS IN THE REGULATION OF MEDICAL DEVICES, AND FOR OTHER PURPOSES

NOVEMBER 6, 1989 AND JULY 17, 1990

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MEDICAL DEVICE SAFETY

MONDAY, NOVEMBER 6, 1989

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:45 a.m. in room 2123, Rayburn House Office Building, Hon. Henry A. Waxman (chairman) presiding.

Mr. WAXMAN. The meeting of the subcommittee will come to order.

Today we will hear testimony about the unnecessary hazard to the public health posed by medical devices. It comes as a shock to learn that in 1989 we have no assurances that the medical devices used in, on and around our bodies are safe and effective.

After all, the Congress enacted legislation for precisely that purpose well over a decade ago, the Medical Device Amendments of 1976. The Food and Drug Administration was charged to enforce the law and assure the public that medical devices were safe.

Today we will hear that serious problems pervade the entire medical device regulatory process from approval of new devices, to monitoring of the devices on the market, to remedies for devices known to be unreasonably safe.

The 1976 law established a comprehensive system for assuring medical devices met high standards. The potentially most dangerous devices were to be approved for safety and effectiveness before they were allowed to go on the market.

No products were permanently grandfathered, even old devices that have been marketed for many years were to undergo reviews to be sure that they were safe and effective. But this has not happened.

The 1976 law allowed all devices that were already being sold to remain available until the FDA finished reviewing their safety and effectiveness. It allowed new versions of the same products to be sold until both the old and new devices were approved.

This provision has been twisted into a dangerous regulatory loophole. The overwhelming majority of old devices have never been reviewed.

Indeed, there is not even a timetable for such reviews. Just as worrisome, a vast majority of new devices, over 95 percent, have been allowed to get on to the market through this loophole without having been approved for safety and effectiveness.

The devices that get into use through this loophole need only show they are substantially equivalent to old devices that were

around before 1976. The result is that new devices are compared only with old devices that have never been shown to be safe and effective.

Other devices that were thought to possess only a moderate risk were to be regulated by assuring they met performance standards. In the 13 years the law has been on the books, FDA has not developed a single performance standard.

Perhaps this incredible laxity in enforcement would not be a serious threat to the public health if we could be confident that the FDA knew about serious problems with devices that were on the market and took quick action to remedy those problems. As we will hear today, the FDA comes up seriously short on both counts.

In 1987, the Government Accounting Office documented the severe shortcomings of the FDA's system for learning about devices that malfunction and injure or kill people. Because the FDA assured us that a new system it was putting into place would overcome these problems, we asked the GAO for a followup study, and in February of this year we heard the bad news.

The system is still not working. FDA is floundering. Only a fraction of the medical device officials that would be expected to report problems, actually do so. One-third of firms don't even know they should report. Many reports that FDA does receive are not being analyzed. Witnesses from the Government Accounting Office will elaborate on those findings today. Their conclusion is clear and of grave concern.

FDA has no early warning system to learn about and correct problems with the medical devices that it lets onto the market without adequate premarket scrutiny.

Most recently we asked the GAO to look at the final link in the regulatory chain, the recall of defective and dangerous devices. Again, the conclusion is unnerving.

Manufacturers of medical devices are keeping potentially unsafe products on the market while the FDA looks the other way. The latest GAO reports show manufacturers who profit from the sale of these products often act without FDA oversight in deciding whether to keep their devices on the market when problems begin to surface.

Even when manufacturers know about problems, problems that are so serious that the use of or exposure to the devices has a reasonable probability of causing serious injury or death, they don't tell FDA in time for the Agency to take action.

This finding flies in the face of FDA Commissioner Frank Young's assurances to the subcommittee that the FDA has all the important information it needs to assure the safety of medical devices.

When FDA doesn't even know about deaths and injuries from products that manufacturers recall, how can the FDA even pretend to know about the safety of thousands of other medical devices that remain on the market?

Since FDA can make independent judgments, how can anyone know how many more products should be recalled that are still in use? With FDA hamstrung, we are at the mercy of manufacturers who alone have the power to decide when to stop selling potentially dangerous products.

The recent GAO reports complete the picture emerging from their earlier studies.

Every stage of the medical device and regulatory process is open to question, from getting products on the market, to learning about serious health consequences from devices in use, to the recall of problem devices. FDA is either unknowing about these problems or in their treatment of many of these issues they are bending over backwards to accommodate the interests of the industry rather than doing its job to protect the public health. It is time for FDA to straighten up and get on with the mission of regulating the medical device industry and promoting the public health.

Today is the first of a series of hearings into the medical device industry. We anticipate our next hearing will include Dr. Frank Young, who is the Commissioner of the Food and Drug Administration.

Before calling on our witnesses, I want to recognize members for opening statements and call on Congressman Rowland.

Mr. ROWLAND. Thank you, Mr. Chairman.

For whatever reasons the postmarket surveillance system does not seem to be working as it should, and I commend you for focusing attention on this. It is distressing to me to know we live in the country that has the best quality of medical care system in the world, but yet we are having a problem with medical devices because there is a distressing, high number of injuries and deaths that are being caused by these medical devices. We certainly need to focus attention on that, get that corrected.

I look forward to the testimony that we have today, and hope we will be able to correct the problem we have with this system and get those devices off the market, get them improved, get them corrected, so we can continue to provide the quality of medical care that people in this country expect.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you very much, Dr. Rowland.

The Chair is pleased to recognize the presence and call upon the chairman of the full committee and chairman of the Oversight and Investigations Subcommittee, Mr. Dingell.

Mr. DINGELL. Mr. Chairman, I thank you for recognition. Mr. Chairman, I also commend you for the hearing today. I am delighted to work with you on these matters. I am here today to signal my very real interest in the issues of this hearing.

This month the Oversight and Investigations Subcommittee will also begin a series of hearings addressing the safety and effectiveness of a number of medical devices and the adequacy of their regulation.

The years since 1976 when the Medical Device Amendments were enacted have been filled with hearings and reports from our two subcommittees. We have heard about faulty pacemaker leads, malfunctioning infant incubators, defective volumetric pumps, and contact lenses. We will continue to hear about apnea monitors which don't work, and lithotripsy machines which apparently work too well, and heart valves which fracture.

It all constitutes a story of regulatory gaps and loopholes, of inadequate Agency scrutiny over new devices and those already on the market, of the reluctance of users to report problems encoun-

tered with devices, and of the failure of industry to act responsibly when such problems occur.

But behind all these case studies and GAO reports is something much more than an inadequate statute, an overburdened Agency, and some unscrupulous manufacturers. Real people—infants, sons, mothers and grandfathers—are dying or suffering serious illness because of medical devices which should not be on the market.

Under such circumstances, exposé hearings are not enough. I intend to end such hearings by enacting the legislation we have needed for so long. I look forward to working with you, Mr. Chairman, to bring our bill, H.R. 3095, to public law in proper format at the earliest moment. Thank you.

Mr. WAXMAN. Thank you very much, Mr. Dingell.

[Testimony resumes on p. 33.]

[The text of H.R. 3095 follows:]

I

101ST CONGRESS
1ST SESSION

H. R. 3095

To amend the Federal Food, Drug, and Cosmetic Act to make improvements in the regulation of medical devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 1989

Mr. WAXMAN (for himself and Mr. DINGELL) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to make improvements in the regulation of medical devices, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND REFERENCE TO ACT.

(a) SHORT TITLE.—This Act may be cited as the "Safe Medical Devices Act of 1989".

(b) REFERENCE.—Whenever in this Act (other than in section 11) an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or

other provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 2. USER REPORTS.

(a) REQUIREMENT.—Section 519 (21 U.S.C. 360i) is amended by redesignating subsection (b) as subsection (c) and by inserting after subsection (a) the following:

"User Reports

"(b)(1)(A) Whenever a medical device user facility receives or otherwise becomes aware of information that reasonably suggests that a medical device may have caused or contributed to the death of, or may have caused or contributed to a life-threatening illness of, or a life-threatening injury to, a patient of the facility, the facility shall promptly report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device.

"(B) Whenever a medical device user facility receives or otherwise becomes aware of information that reasonably suggests that a medical device has malfunctioned or will malfunction and such malfunction would be likely to cause or contribute to the death or serious illness of, or serious injury to, a patient of the facility, the facility shall promptly report the information to the Secretary, and if the identity of the manufacturer is known, to the manufacturer of the device.

"(C) Each medical device user facility shall submit to the Secretary on a quarterly basis a summary of the reports

made under subparagraphs (A) and (B). Such a summary shall be in such form and contain such information from such reports as the Secretary may require and shall at least include—

"(i) sufficient information to identify the facility which made the reports for which the summary is submitted,

"(ii) in the case of any product which was the subject of a report, identification of the product name, serial number, and model number,

"(iii) the name and the address of the manufacturer of such device, and

"(iv) a brief description of the event reported to the manufacturer.

"(D) For purposes of subparagraphs (A), (B), and (C), a facility shall be treated as having received or otherwise become aware of information with respect to a medical device of that facility when an individual who is employed by or otherwise affiliated with the facility receives or otherwise becomes aware of information with respect to that device in the course of their duties.

"(2) The Secretary may not disclose the identity of a facility which makes a report under paragraph (1)—

"(A) except in connection with an action brought to enforce section 301(q),

"(B) except in connection with a communication to a manufacturer of a device which is the subject of a report under paragraph (1), or

"(C) unless required to be disclosed under subsection (a).

This paragraph does not authorize the Secretary to withhold the identity of a facility making a report under paragraph (1) or any information in such a report from the duly authorized committees and subcommittees of the Congress.

"(3) No medical device user facility and no individual who is employed by or otherwise affiliated with such a facility shall be held liable in any private civil action with respect to the content of any report made under paragraph (1) unless the individual or facility had knowledge of the falsity of the information contained in the report. A report made under paragraph (1) respecting a device or the fact that such a report has been made may not be admitted into evidence or otherwise used in an action against a medical device user facility other than an action brought to enforce this subsection.

"(4) No medical device user facility may—

"(A) discharge or take any other adverse personnel action with respect to any employee because the employee made a report to an officer or employee of the facility respecting a device, or

"(B) limit the practice of, or take any other adverse action with respect to, any practitioner because the practitioner made a report to an officer or employee of the facility respecting a device.

"(5)(A) Any medical device user facility which knowingly fails to make a report in accordance with paragraph (1) shall be subject to a civil penalty of not more than $10,000 for each day in which such failure to report occurs, except that the maximum amount of a civil penalty for any failure to report may not exceed $500,000.

"(B) Section 303 shall not apply to a violation of the requirements of this subsection.

"(6) A report made under paragraph (1) respecting a device does not affect any obligation of the manufacturer of the device who receives the report to file a report as required under subsection (a) respecting the device.

"(7) For purposes of this subsection, the term "medical device user facility" means a hospital, ambulatory surgical facility, outpatient diagnostic or treatment facility which is not a physician's office, or a nursing home.".

(b) SANCTION.—Section 302 (21 U.S.C. 332) is amended—

(1) in subsection (a) by inserting "(1)" before "to restrain", and

(2) by inserting before the period at the end of subsection (a) the following: ", and (2) of civil actions brought by any individual against a medical device user facility for damages for actions taken against the individual in violation of section 519(b)(4)".

(c) REGULATIONS.—The Secretary of Health and Human Services shall promulgate regulations to implement section 519(b) of the Federal Food, Drug, and Cosmetic Act, added by subsection (a) of this section, not later than 12 months after the date of the enactment of this Act.

(d) EFFECTIVE DATE.—

(1) Section 519(b) of the Federal Food, Drug, and Cosmetic Act (other than paragraph (5) of such section), as added by subsection (a), shall take effect—

(A) upon the effective date of regulations promulgated under subsection (c), or

(B) upon the expiration of one year from the date of the enactment of this Act,

whichever occurs first.

(2)(A) The Secretary of Health and Human Services shall conduct a study of compliance with the requirements of section 519(b) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), by hospitals, ambulatory surgical facilities, outpatient diagnostic or treatment facilities which are not physi-

cians' offices, and nursing homes. The Secretary shall report the results of the study to the Congress after the expiration of 45 months after the date of the enactment of this Act.

(B)(i) If upon the expiration of 48 months after the date of the enactment of this Act the Secretary has not made the report required by subparagraph (A), paragraph (5) of such section 519(b) shall take effect upon the expiration of such months.

(ii) If in the report under subparagraph (A) the Secretary reports that there has been substantial compliance with the requirements of such section 519(b) by hospitals, ambulatory surgical facilities, outpatient diagnostic or treatment facilities which are not physicians' offices, or nursing homes and if the Secretary does not make a determination under clause (iii) with respect to such hospitals, ambulatory surgical facilities, outpatient facilities, or nursing homes, such paragraph (5) shall not take effect with respect to such hospitals, ambulatory surgical facilities, outpatient facilities, or nursing homes.

(iii) If—

(I) in the report under subparagraph (A) the Secretary determines, or

(II) after making the report under subparagraph (A) the Secretary determines by regulation, that there is not substantial compliance with the requirements of such paragraph (5) by hospitals, ambulatory surgical facilities, outpatient facilities, or nursing homes, such paragraph (5) shall take effect with respect to such hospitals, ambulatory surgical facilities, outpatient facilities, or nursing homes upon the effective date of the regulation.

(e) EDUCATION AND INFORMATION.—During the one-year period beginning on the date of the enactment of this Act the Secretary shall conduct education and information programs for hospitals, ambulatory surgical facilities, outpatient diagnostic or treatment facilities which are not physicians' offices, and nursing homes respecting the requirements of section 519(b) of the Federal Food, Drug, and Cosmetic Act.

(f) STUDY.—Three years after the date of the enactment of this Act the Comptroller General of the United States shall conduct a study of—

(1) the compliance by hospitals, ambulatory surgical facilities, outpatient diagnostic or treatment facilities which are not physicians' offices, and nursing homes with the requirements of section 519(b) of the Federal Food, Drug, and Cosmetic Act, and

(2) the actions taken by the manufacturers of devices in response to reports made to them under such section.

The Comptroller General shall complete the study and submit a report on the study not later than 3 months before the expiration of 4 years from the date of the enactment of this Act. The report shall be submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate and to the Secretary of Health and Human Services.

SEC. 3. REPORTS.

(a) INCLUSION OF DISTRIBUTORS.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall amend the regulations published as part 803 of title 21 of the Code of Federal Regulations to require distributors of medical devices to establish and maintain records and make reports under section 519 of the Federal Food, Drug, and Cosmetic Act.

(b) COPIES TO MANUFACTURERS.—Section 519(a)(3) (21 U.S.C. 360i(a)(3)) is amended by inserting before the semicolon the following: "and shall require distributors who submit such reports to submit copies of the reports to the manufacturer of the device for which the report was made".

(c) CERTIFICATION, USER TRACKING.—Section 519 (21 U.S.C. 360i) is amended by adding at the end the following:

"Certification

"(c) Each manufacturer, importer, and distributor required to make reports under subsection (a) shall submit to the Secretary annually a statement certifying that—

"(1) the manufacturer, importer, or distributor did not file any report under subsection (a) because it did not receive information respecting, or was not aware of, events requiring such a report, or

"(2) the manufacturer, importer, or distributor did file a certain number of such reports which represented all events concerning which the manufacturer, importer, or distributor had information.

"User Tracking

"(d)(1) The Secretary shall by regulation require every person who registers under section 510 and is engaged in the manufacture of a class III device to assign a model or other identification number to each such device and to maintain records that identify—

"(A) the retailers, medical device user facilities, and other establishment or individuals to which or whom such devices are sold, and

"(B) the date on which the device was sold.

"(2) The Secretary shall by regulation require every manufacturer, retailer, medical device user facility, or other individual or entity which sells or uses a class III device to maintain records that identify by model or other identification number each such device which is sold or provided to ensure that patients who receive such devices can be provided the notification authorized by section 518.".

(d) PROHIBITED ACTS.—Section 301(q)(2) (21 U.S.C. 331(q)(2)) is amended by inserting after the comma the following: "the failure or refusal to submit any report required by or under this Act or".

SEC. 4. PREMARKET APPROVAL.

(a) SUBSTANTIAL EQUIVALENCE.—

(1) Section 520 (21 U.S.C. 360j) is amended by adding at the end the following:

"Substantial Equivalence

"(m) For purposes of sections 513 and 515 and this section, a device may be considered to be substantially equivalent to another device only if the Secretary by order finds—

"(A) the device has the same intended use and the same technological characteristics as such other device, or

"(B) the device has the same intended use as such other device but has different technological characteristics and the evidence submitted that the device is sub-

stantially equivalent to such other device contains information, including clinical data if required by the Secretary, demonstrating that the device with such different technological characteristics is as safe and effective as comparable devices which are currently being sold in interstate commerce.

For purposes of this paragraph, technological characteristics of a device shall be considered to be different from those of the device to which it is being compared if there is a significant change in the materials, design, energy source, or other features from those of the device to which it is being compared.".

(2) Section 520(h)(1) (21 U.S.C. 360j(h)(1)) is amended by striking out "or" at the end of subparagraph (B), by adding "or" after the comma at the end of subparagraph (C), and by adding after subparagraph (C) the following:

"(D) an order under subsection (m) finding that a device is substantially equivalent to another device,".

(3) Section 513(f) (21 U.S.C. 360c(f)) is amended—

(A) effective 5 years after the date of the enactment of this Act, by striking out subclause (I) of paragraph (1)(A)(i), and

(B) by adding at the end the following:

"(3) If a manufacturer reports to the Secretary under section 510(k) that a device is not a class III device under paragraph (1) because the device is substantially equivalent to another device within a type of device—

"(i) which the Secretary has classified as a class III device under subsection (b),

"(ii) which was introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this paragraph, and

"(iii) for which no final regulation requiring premarket approval has been promulgated under section 515(b),

the manufacturer shall certify to the Secretary that the manufacturer has conducted a reasonable search of all information known to the manufacturer and of all published information respecting such other device and has included in the report under section 510(k) a description of and a citation to all adverse safety and effectiveness data respecting such other device and respecting the device for which the 510(k) report is being made and which has not been submitted to the Secretary under section 519. The Secretary may require the manufacturer to submit the adverse safety and effectiveness data described in the report.".

(b) REVISION OF CLASSIFICATION.—

(1) Section 515 (21 U.S.C. 360e) is amended by adding at the end the following:

"Revision

"(i)(1) Before the expiration of 5 years after the date of the enactment of this subsection, the Secretary shall by order require manufacturers of devices, which are subject to revision of classification under paragraph (2), to submit to the Secretary a description of and citation to any adverse safety or effectiveness information known to the manufacturers respecting the devices which has not been submitted under section 519. The Secretary may require a manufacturer to submit the adverse safety and effectiveness data for which a description and citation was submitted to the Secretary.

"(2) After the issuance of an order under paragraph (1) but before the expiration of 5 years after the date of the enactment of this subsection, the Secretary shall publish a notice in the Federal Register for each device—

"(A) which the Secretary has classified as a class III device,

"(B) which was introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section, and

"(C) for which no final regulation has been promulgated under section 515(b),

revising the classification of the device so that the device is classified into class I unless the notice requires the device to remain in class III or revises the classification of the device so that the device is classified into class II. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 513(a). Before the publication of a notice requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed notice respecting the classification of a device under this paragraph and provide reasonable opportunity for the submission of comments on any such notice. No notice requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from the date of its publication in the Federal Register as a proposed notice. Any person adversely affected by such a final notice under this paragraph may challenge the retention of a device in class III or the revision of its classification only by filing a petition under section 513(e) for a classification change.".

(2) Section 515(a) (21 U.S.C. 360e(a)) is amended by striking out "; or" at the end of paragraph (1) and inserting in lieu thereof a comma and by adding after paragraph (2) the following:

"(3) for which the Secretary has published a notice under subsection (i)(2) requiring such device to remain in class III, or

"(4) for which the Secretary has not, within 5 years of the date of the enactment of the Safe Medical Devices Act of 1989, published a notice under subsection (i)(2),".

(3) Section 520(l) (21 U.S.C. 360j(l)) is amended by adding at the end the following:

"(5)(A) Before the expiration of 1 year after the date of the enactment of this paragraph, the Secretary shall by order require manufacturers of devices, which are subject to revision of classification under subparagraph (B), to submit to the Secretary a description of and citation to any adverse safety or effectiveness information known to the manufacturers respecting the devices which has not been submitted under section 519. The Secretary may require a manufacturer to submit the adverse safety and effectiveness data for which a description and citation was submitted to the Secretary.

"(B) Except as provided in subparagraph (C), after the issuance of an order under subparagraph (A) but before the expiration of 2 years after the date of the enactment of this paragraph, the Secretary shall publish a notice in the Federal Register for each device which is classified in class III under paragraph (1) revising the classification of the device so that

the device is classified into class I unless the notice requires the device to remain in class III or revises the classification of the device so that the device is classified into class II. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 513(a). Before the publication of a notice requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed notice respecting the classification of a device under this subparagraph and provide reasonable opportunity for the submission of comments on any such notice. No notice under this subparagraph requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from the date of its publication in the Federal Register as a proposed notice. Any person adversely affected by a final notice under this subparagraph revising the classification of a device may challenge the revision of the classification of the device only by filing a petition under section 513(e) for a classification change.

"(C) The Secretary may by notice published in the Federal Register extend the 2-year period prescribed by subparagraph (B) for a device for an additional period not to exceed 1 year.".

(c) JUDICIAL REVIEW.—Section 517(a)(1) (21 U.S.C. 360g(a)(1)) is amended—

(1) in paragraph (1), by striking out "section 513 classifying a device in class I or changing the classification of a device to class I or an order" and inserting in lieu thereof "section 513(e) classifying a device or changing the classification of a device or the issuance of an order",

(2) by striking out "or" at the end of paragraph (6),

(3) by adding "or" at the end of paragraph (7), and

(4) by adding after paragraph (7) the following:

"(8) an order under section 520(m) finding that a device is substantially equivalent to another device,".

(d) CONFORMING AMENDMENT.—Section 301(q)(1) (21 U.S.C. 331(q)(1)) is amended by striking out "519 or 520(g)" and inserting in lieu thereof "513(f)(3), 515(i)(1), 519, 520(g), or 520(l)(5)(A)".

SEC. 5. CLASSIFICATION AND RECLASSIFICATION OF DEVICES.

(a) STANDARDS.—

(1) Section 513(a)(1)(A)(ii) (21 U.S.C. 360c(a)(1)(A)(ii)) is amended by striking out "or to establish a performance standard" and inserting in lieu thereof "or to apply special controls".

(2) Section 513(a)(1)(B) is amended to read as follows:

"(B) CLASS II, SPECIAL CONTROLS.—A device which cannot be classified as a class I device because the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information about a device such that the Secretary may apply special controls, including the promulgation of performance standards, development and dissemination of guidelines, recommendations, and other appropriate actions by the Secretary as the Secretary deems necessary to provide such assurance.".

(3) Clause (i) of section 513(a)(1)(C) is amended to read as follows:

"(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the application of special controls described in

subsection (b) would provide reasonable assurance of its safety and effectiveness, and,".

(b) EVIDENCE.—Section 513(e) is amended by inserting "(1)" after "(e)" and by adding at the end the following:

"(2) By regulation promulgated under paragraph (1), the Secretary may change the classification of a device from class III—

"(A) to class II if the Secretary determines that special controls would provide reasonable assurance of the safety and effectiveness of the device and that general controls would not provide reasonable assurance of the safety and effectiveness of the device, or

"(B) to class I if the Secretary determines that general controls for the device would provide reasonable assurance of the safety and effectiveness of the device.".

SEC. 6. ESTABLISHMENT OF PERFORMANCE STANDARDS.

(a) PROCEDURE.—

(1) The last sentence of section 513(a)(1) (21 U.S.C. 360c(a)(1)) is inserted as the last sentence of section 514(a) (21 U.S.C. 360d(a)).

(2) Subsections (b) through (f) of section 514 (21 U.S.C. 360d) are repealed.

(3) Subsection (g) of such section is redesignated as subsection (b).

(4) Subsection (b) (as so redesignated) of such section is amended by striking out paragraphs (1) and (2), by redesignating paragraphs (3), (4), and (5) as paragraphs (2), (3), and (4), respectively, and by inserting before paragraph (2) the following:

"(b)(1) A notice of proposed rulemaking for the establishment of a performance standard for a device shall—

"(A) set forth a finding by the Secretary that the performance standard is both appropriate and necessary for the device,

"(B) set forth proposed findings with respect to the degree of the risk of illness or injury designed to be eliminated or reduced by the proposed performance standard and the benefit to the public from the device,

"(C) provide an opportunity to submit to the Secretary a request (within 15 days of the date of the publication of the notice) for a change in the classification of the device based on new information relevant to its classification, and

"(D) invite the submission of an existing performance standard as a proposed performance standard for the device.".

(b) CONFORMING AMENDMENTS.—

(1) Paragraph (2) of subsection (b) (as so redesignated) of such section is amended by striking out

"paragraph (2)" and inserting in lieu thereof "paragraph (1)".

(2) Paragraph (3)(A) of such subsection (as so redesignated) is amended by striking out "paragraphs (2) and (3)(B)" and inserting in lieu thereof "paragraphs (1) and (2)(B)".

SEC. 7. NOTIFICATION AND OTHER REMEDIES.

(a) STANDARD FOR REPAIR, REPLACEMENT, AND REFUND.—Section 518(b)(1)(A) (21 U.S.C. 360h(b)(1)(A)) is amended by striking out clause (ii) and by redesignating clauses (iii) and (iv) as clauses (ii) and (iii), respectively.

(b) Section 519 (21 U.S.C. 360i) (as amended by section 2) is amended by adding at the end the following:

"Reports of Removals and Field Repairs

"(d)(1) Except as provided in paragraph (2), the Secretary shall by regulation require a manufacturer, importer, or distributor of a device to report to the Secretary any removal or field repair of a device undertaken by the manufacturer, importer, or distributor of a device if the removal or field repair was undertaken to—

"(A) eliminate a risk to health posed by the device, or

"(B) remedy a violation of this Act caused by the device.

A manufacturer, importer, or distributor of a device who undertakes a field repair or removal of a device which is not required to be reported under this paragraph shall keep a record of such field repair or removal.

"(2) No report of the field repair or removal of a device may be required under paragraph (1) if a report of the field repair or removal is required, and has been submitted, under subsection (a).

"(3) For purposes of paragraphs (1) and (2), the terms 'field repair' and 'removal' do not include routine servicing.".

SEC. 8. REMANUFACTURE.

Section 510(a) (21 U.S.C. 360(a)) is amended—

(1) by striking out "and" at the end of paragraph (1) and by striking out the period at the end of paragraph (2) and inserting in lieu thereof "; and", and

(2) by adding after paragraph (2) the following:

"(3) the term 'manufacture' includes remanufacture and the term 'remanufacture' means the fabrication, assembly, substantial alteration, processing, or reprocessing of a device which has been previously introduced into interstate commerce if the fabrication, assembly, substantial alteration, processing, or reprocessing is not part of routine service on the device.".

SEC. 9. EDUCATION AND TRAINING.

Section 520 (21 U.S.C. 360j) is amended by adding at the end the following:

"Education and Training

"(n) The Secretary shall plan, conduct, coordinate, and support education, training, and operational activities to minimize the exposure of people to the health hazards associated with devices.".

SEC. 10. MISCELLANEOUS.

(a) SECTION 513(a)(3)(A).—Section 513(a)(3)(A) 21 U.S.C. 360c(a)(3)(A)) is amended by inserting after "well-controlled investigations" the following: "irrespective of the sponsor of the investigations".

(b) SECTION 513(f).—Section 513(f)(2) (21 U.S.C. 360c(f)(2)) is amended in subparagraph (B)(i), by striking out "the Secretary shall" and inserting in lieu thereof "the Secretary may for good cause shown".

(c) SECTION 514.—Section 514(b) (21 U.S.C. 360d(b)(4)(B)) (as so redesignated) is amended—

(1) in paragraph (3)(B) (as so redesignated), by striking out ", after affording all interested persons an opportunity for an informal hearing,", and

(2) in clause (ii) of paragraph (4)(A) (as so redesignated), by striking out "unless" and all that follows in that clause and inserting in lieu thereof the following: "which demonstrates good cause for referral and which

is made before the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation,".

(d) SECTION 515.—Section 515(c)(2) (21 U.S.C. 360e(c)(2)) is amended by striking out "paragraph (1), the Secretary shall refer such application" and inserting in lieu thereof "paragraph (1), the Secretary—

"(A) may on the Secretary's own initiative refer such application, or

"(B) shall, upon the request of an applicant unless the Secretary finds that the information in the application which would be reviewed by a panel substantially duplicates information which has previously been reviewed by a panel appointed under section 513, refer such application,".

(e) SECTION 516.—Section 516(a) (21 U.S.C. 360f(a)) is amended (1) by striking out "and after consultation with the appropriate panel or panels under section 513", and (2) by striking out the last sentence.

(f) SECTION 520(l).—Section 520(l)(2) (21 U.S.C. 360j(l)(2)) is amended by striking out "and after affording the petitioner an opportunity for an informal hearing".

SEC. 11. ELECTRONIC PRODUCTS.

(a) IN GENERAL.—Subpart 3 of part F of title III of the Public Health Service Act is transferred to chapter V of

the Federal Food, Drug, and Cosmetic Act, is placed after section 528, and is amended as follows:

(1) The heading for the subpart is amended to read as follows:

"SUBCHAPTER C—ELECTRONIC PRODUCT RADIATION CONTROL".

(2) The subpart is amended by striking out "subpart" each place it occurs and inserting in lieu thereof "subchapter".

(3)(A) Section 356 of such Act is amended—

(i) by striking out "358" each place it occurs and inserting in lieu thereof "534", and

(ii) by striking out "sections 3648 and 3709 of the Revised Statutes of the United States (31 U.S.C. 529, 41 U.S.C. 5)" and inserting in lieu thereof "section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes of the United States (41 U.S.C. 5)".

(B) Section 358(a)(1)(E) of such Act is amended by striking out "355" and inserting in lieu thereof "531".

(C) Section 359 of such Act is amended—

(i) by striking out "358" each place it occurs and inserting in lieu thereof "534", and

(ii) by striking out "360A" each place it occurs and inserting in lieu thereof "536".

(D) Section 360 of such Act is amended by striking out "358" each place it occurs and inserting in lieu thereof "534".

(E) Section 360A of such Act is amended—

(i) by striking out "358" and inserting in lieu thereof "534", and

(ii) by striking out "359" each place it occurs and inserting in lieu thereof "535".

(F) Section 360B of such Act is amended—

(i) by striking out "358" each place it occurs and inserting in lieu thereof "534",

(ii) by striking out "359" each place it occurs and inserting in lieu thereof "535", and

(iii) by striking out "360A" each place it occurs and inserting in lieu thereof "536".

(G) Section 360C of such Act is amended—

(i) by striking out "358" and inserting in lieu thereof "534",

(ii) by striking out "360B" each place it occurs and inserting in lieu thereof "537", and

(iii) by striking out "360F" and inserting in lieu thereof "542".

(H) Section 360F of such Act is amended by striking out "358" and inserting in lieu thereof "534".

(4) Section 354 of such Act is repealed and sections 355 through 360F of such Act are redesignated as sections 531 through 542, respectively.

(b) CONFORMING AMENDMENT.—The heading for part F of title III of the Public Health Service Act is amended by striking out "AND CONTROL OF RADIATION".

(c) CONSTRUCTION.—The transfer of subpart 3 of part F of title III of the Public Health Service Act to the Federal Food, Drug, and Cosmetic Act does not change the application of the requirements of such subpart and such Act to electronic products which were in effect on the date of the enactment of this Act.

SEC. 12. APPLICATION.

Medical devices used to deliver electro-convulsive therapy shall be subject to sections 513 through 521 of the Federal Food, Drug, and Cosmetic Act as in effect on the day before the date of the enactment of this Act.

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Mr. WAXMAN. It is a special privilege to welcome as our first witness this morning, the Comptroller General of the United States, the Honorable Charles Bowsher. It is clear evidence of the gravity of medical device reform that the Comptroller General has taken the time from his other duties to appear before the subcommittee.

We want to welcome Ms. Eleanor Chelimsky, Assistant Comptroller General, U.S. General Accounting Office. Mr. Bowsher and Mr. Chelimsky are accompanied by Gerald Dillingham, Project Manager, U.S. General Accounting Office.

Without objection, your prepared statements will be a part of the record. We will ask you to make oral presentations to us.

STATEMENTS OF CHARLES A. BOWSHER, COMPTROLLER GENERAL, AND ELEANOR CHELIMSKY, ASSISTANT COMPTROLLER GENERAL, GENERAL ACCOUNTING OFFICE

Mr. BOWSHER. Mr. Chairman and members of the committee, we are pleased to be here today. We appreciate very much your putting our formal testimony in the record. I would like to summarize, if I could, our major findings.

As you are aware, since 1986, we have issued seven separate reports on this issue. I would like to break the summary into two or three parts.

One is on premarket testing. Here we have had 36,000 devices enter the market since 1976. Only 6 percent were required to pass tests, whereas the FDA judged 94 percent to be substantially equivalent. Therefore, they were not put through the testing process.

We see four problems basically with this situation. One is that many of the pre-1976 devices were never tested themselves. Two, you have use of an old and often outdated comparison base. Three, you have a lack of definition of what is substantial equivalence. Four, FDA's failure to develop standards for medium risk devices or to implement premarket requirements for high risk devices.

So, the end result of the premarket testing is only a few high-risk devices have been subjected to real scrutiny.

On postmarket reporting, whose purpose is to get early warning of problems, you have four major components of the postmarket surveillance system.

One is the voluntary reporting of problems by users to FDA. Two is the mandatory reporting by manufacturers to FDA. Three is the monitoring and analysis of the problems by the FDA. Four is the recall or removal of devices from the market.

The weaknesses before 1984 of the postmarket review go something like this. FDA knew of fewer than 1 percent of the device problems that had occurred in the hospitals. Only 51 percent of the problems were reported to any outside organization, but mostly they were reported to the manufacturers.

Most reporting, as much as 83 percent was really done verbally rather than in written communication. After the 1984 reporting change regulations went into effect, we had improvement in reporting. We went from 2,500 to 18,000 reported situations. But after we reviewed this situation, we found only about one-fourth of the manufacturers were reporting. One-third of the manufacturers inspected by FDA said that they didn't even know they should report.

What is more disturbing probably is that FDA's processing system, after getting more reporting, really was not adequate to handle it. The analysis of the data did not produce results most of the time.

One of the things we are recommending today in the reports that we are issuing is some additional reporting. We believe it would be very important if each manufacturer were required to issue an annual report citing the major problems that have been reported to them and what has been done by them. And also, we believe the FDA inspection should be done on a sound, statistical basis in the future so that we know what percentage of the problem is being reported.

Even with 18,000 reports coming in now after 1984, we still don't know what percent of the problem we are hearing about. Therefore, we don't know what the extent of this problem really is.

So these are our main recommendations. These are the summaries. As you have outlined very well, Mr. Chairman, we feel it is a very serious situation.

I would now like to have my colleague, Eleanor Chelimsky, summarize her statement.

[The prepared statement of Mr. Bowsher follows:]

STATEMENT OF CHARLES A. BOWSHER

Mr. Chairman and Members of the Subcommittees, it in a pleasure to be here this morning to discuss our evaluations of the Food and Drug Administration's [FDA] systems of premarket review and postmarket surveillance of medical devices sold in the United States.

Medical devices run the gamut from the very simple to the extremely complex from common household items such as thermometers and bandages to kidney dialysis machines and implanted heart valves. Devices such as artificial hips, intraocular lenses, and hearing aids increase the independence and improve the quality of life of many. Diagnostic devices such as the magnetic resonance imaging machine have increased the speed and accuracy of diagnosis and, in some cases, have replaced more dangerous procedures. More than 1,700 different types of medical devices are available in the United States today, millions of Americans come into contact with them, and these devices represent an industry of more than $14 billion annually.

Since passage of the Food and Drugs Act in 1906, the Congress has shown concern for the protection of the public from the harmful effects of contaminated food and unsafe or ineffective drugs. In 1938, coverage was extended to the regulation of cosmetics and medical devices in the Federal Food, Drug, and Cosmetic Act, legislation which is still the basis for FDA's operations.

During the late 1960's and early 1970's, public concern about the safety and effectiveness of medical devices continued to increase. A study group, which became known as the Cooper Committee, was formed by the Department of Health, Education, and Welfare to examine the issues and make legislative recommendations. Many of the committee's recommendations are reflected in the Medical Device Amendments of 1976, which currently provide the basis for FDA's pre- and postmarket systems for regulating devices. The amendments call for the classification of medical devices according to three degrees of potential risk—low, medium, and high—and each device was to be classified and regulated according to what was needed to reasonably ensure its safety and effectiveness.[1]

[1] These terms, which we have adopted for the sake of clarity, correspond to the three FDA-defined device classes in the following ways: low-risk devices are class 1 devices, those subject to minimum FDA regulation such as registration, premarket notifications and adherence to good manufacturing practices; medium-risk devices are class 2, those where performance standards are believed necessary to assure safety and effectiveness; and high-risk devices are class 3, those viewed as potentially very hazardous and that usually require FDA approval before marketing. Finally, in addition to the requirements for their respective classes, all devices are subject to the requirements for class 1 devices.

Since 1986, the General Accounting Office [GAO] has examined the major components of both these systems (including selected regulations developed to implement the amendments), issued seven separate reports, and testified before this subcommittee about our findings.[2] Today I present an overview of our work to date, including the major recommendations we have made for improving the effectiveness of FDA systems and the underlying regulations.[3] In the testimony that follows, Eleanor Chelimsky, Assistant Comptroller General for Program Evaluation and Methodology, will discuss some of our findings in greater detail and, in particular, will share with you the results of ongoing work that examines some issues related to the resolution of identified medical device problems.

In brief, our work reveals several shortcomings in both the premarket review and postmarket surveillance systems for medical devices and raises serious questions about the ability of these systems and related regulations to protect the American people from unsafe and ineffective medical devices.

With regard to the premarket review system, we (as well as the subcommittee) are concerned about the large number of devices that reach the market after only a relatively cursory review. And within the FDA's postmarket surveillance systems we also discovered two major problem areas. First, there was a severe shortage of information about the nature and scope of problems associated with the devices once they had become available in the marketplace and began to be used. Second, when information about problems encountered in using devices was available, FDA's ability to deal with that information and take efficient and effective remedial action was questionable.

Now that I have broadly stated our concerns with FDA's premarket review and postmarket surveillance systems, I would like to turn to a more detailed description of our work in these areas, with a special emphasis on the evidence that supports our conclusions and our recommendations to this subcommittee. Let me begin with the premarket review system and then turn to the system of postmarket surveillance.

Since passage of the Medical Device Amendments of 1976, roughly 36,000 devices and device modifications have been allowed to enter the market. All followed one of two routes. One group of devices was approved if valid scientific procedures showed evidence of their safety and effectiveness. This route is known as premarket approval. In practice, this usually meant that the manufacturer had to conduct clinical trials of the device. However, only six percent of all medical devices entering the market between 1976 and 1986 were required to pass these rigorous scientific tests. Another group of devices, 94 percent of the total, was reviewed and allowed to enter the market after FDA judged them to be substantially equivalent to devices already on the market before 1976. For almost all of these devices, no direct evidence of safety or effectiveness was required, just support for the manufacturer's claim of equivalence.

This subcommittee has expressed concern about the large number of devices that reach the market based on their substantial equivalence to older devices already available to the public, rather than on direct evidence of their own safety and effectiveness. This is a concern we share. At the current time, the manufacturers of most devices, regardless of the device's level of risk, can market their products 90 days after notifying FDA that their devices are substantially equivalent to a product that was available prior to 1976. If FDA decides that the proposed device is substantially equivalent to one marketed before 1976, the new device can be marketed immediately. Therefore, the concept of substantial equivalence and the way it has been applied by FDA are very crucial elements in the decision process.

We see four principal issues that need to be addressed in the current premarket review system: (1) the fact that the pre-1976 devices to which new ones are found substantially equivalent may never themselves have been tested at all; (2) the use of an old and often outdated comparison base (of pre-1976 devices) for determining substantial equivalence; (3) the lack of a definition of substantial equivalence; and (4) FDA's failure both to develop the mandated performance standards for medium-risk devices and to implement premarket approval requirements for pre-1976 high-risk devices.

The first issue is the apparent working assumption that most pre-1976 medical devices are safe and effective and thus an appropriate basis for substantial equiva-

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[2] The seven reports and the testimony are listed in appendix I.

[3] Much of the information in this testimony is derived from our previous reports and thus represents the state of medical device regulation at the time the studies were completed. Although we have continued to monitor PDA's progress, we have not conducted a complete and formal followup review of the agency's actions on topics covered in our earlier reports.

lency determinations. But a number of empirical studies conducted prior to 1976, including the Cooper Committee's work, found that marketed medical devices had been associated with hundreds of deaths and 10,000 injuries over a 10-year period. Thus, it is not valid to assume that simply because a device has been on the market for a long time, there is no need to prove its safety and effectiveness. This is especially the case for those pre-1976 devices that panels of experts classified as high-risk because they felt the devices should go through premarket approval to prove their safety and effectiveness.

Second, the statutory requirement that a device be compared to a pre-1976 counterpart ignores the possibility that there may be a newer similar device currently on the market that, because of the technological advances it represents, is safer or more effective than the pre-1976 comparison device. As the comparison base recedes into the more and more distant past, the current process for substantial equivalence determinations could lead to the approval of devices that are increasingly out-of-date technologically. Further, and even more importantly, the requirement for comparison with pro-1976 devices provides little incentive for manufacturers to emphasize leading-edge technology.

Third, the statute does not define the term "substantial equivalence" and the legislative history is open to at least two different interpretations. One interpretation is that when a device about to be marketed varies from pre-1976 devices in its materials, designs, or energy source, the product should be found not substantially equivalent. A second interpretation is that only when a device varies from pre-1976 devices in ways that can materially affect safety or effectiveness should it be labeled not substantially equivalent. This second interpretation, the one usually followed by FDA, allows the agency to declare that devices with apparently major differences (in materials, design, or energy source) from pre-1976 devices are substantially equivalent to those devices. Conversely, a literal application of the first interpretation would result in considerably fewer devices being found substantially equivalent.

As a result of our review of these issues, we have suggested that if the Congress is concerned about the way in which FDA interprets the term substantial equivalence, it may want to consider providing a statutory definition of that term. In addition, we have recommended that the Congress amend the Federal Food, Drug, and Cosmetic Act to shift the comparison base from devices introduced prior to 1976 to currently marketed devices.

The fourth issue in the current permarket review system that needs to be addressed in FDA's failure to develop performance standards for medium-risk devices and to implement premarket approval for high-risk devices. The act mandates that FDA develop and apply performance standards for all medium-risk devices and that the Agency approve the safety and effectiveness of all high-risk devices before they reach the market. To date, FDA has not developed any formal performance standards for medium-risk devices and, since 1976, has required premarket approvals for only 9 of 150 types of high-risk devices.

The result of this failure to implement the statutory requirements is that while a few high-risk devices are subjected to full scrutiny, the majority of high- and all medium-risk devices are treated as if they were low-risk. The agency simply declares them to be substantially equivalent to pre-1976 devices, which may themselves never have been approved and allows them to go immediately to market. The result is that 141 types of high-risk devices may be put into use with no premarket approval. And for 854 types of medium-risk devices there is, in the absence of performance standards, no middle ground in how they are reviewed. Almost all are declared to be substantially equivalent to pre-1976 devices and are put into use with no evidence of having met performance or safety standards. Although the 13-year-old statute set no timetable for full implementation of differential treatment of medium-rink and high-rink devices, we believe FDA's progress has been clearly inadequate.

The FDA staff time needed to implement these requirements would be considerable, and thus we recommended in our report that the Congress should consider alternatives to the full-scale approaches currently called for in the statute. For example, it may be appropriate to reclassify some types of medium-risk devices as low-risk and to adopt voluntary industry standards for others rather than have FDA develop them. FDA could then concentrate on developing performance standards only for the riskiest of medium-risk devices.

Now I would like to discuss our findings with regard to the existing postmarket surveillance system. But first let me point out that no premarket review system, even the most thorough imaginable, can guarantee that there will be no problems when medical devices are put into widespread use. Thus, the purpose of FDA's postmarket surveillance system is to provide "early warning" of problems associated

with devices in use. The intent is to identify serious incidents rapidly and then to act upon recurring problem-causes such as manufacturing defects, unanticipated user errors, poorly written instruction manuals, and latent device-design problems.

The postmarket surveillance system has four main components: (1) voluntary reporting of problems by the users to FDA, to the manufacturer, or to various intermediaries; (2) mandatory reporting of known problems by manufacturers to FDA; (3) monitoring and analysis of problems by FDA; and (4) a recall process that may result in either corrective action or removal of the device from the market.

For postmarket surveillance to work, information about device problems must be promptly and accurately transmitted to FDA, the Agency must be able to analyze the data and identify the problems, and there must be a systematic process by which FDA decides upon the appropriate level of action. In our review of FDA's system, we found several weaknesses in these three areas.

First, with regard to the transmission of information, in a study of 10 medical devices used in hospitals, we found reason for serious concern.[4] Our analysis revealed that FDA knew about fewer than 1 percent of the device problems that had occurred in the hospitals. And one of the more disturbing aspects of this situation was that hospital personnel reported to us that they were more likely not to report a problem that involved a patient injury than they were one that did not.

We concluded that FDA's lack of information about problems with medical devices had three specific sources: problems were not always reported; only 51 percent of the device problems known to hospital personnel were reported to any outside organization; of the information about problem devices that was reported almost all (92 percent) went to manufacturers or intermediaries (for example, distributors and service centers), but almost none was passed on to the FDA; and finally, of the reports actually made on device problems, 83 percent were transmitted exclusively in oral fashion.

Although hospitals took action locally to avoid a recurrence in 85 percent of the problem cases; the FDA was severely limited in its ability either to understand the scope of device problems or to implement systemic solutions such as the recalling of defective devices.

As a result of our findings, we recommended that FDA attempt to increase the quantity and quality of information available for monitoring device problems by requiring the distributor of medical devices to report problem information to manufacturers. We also recommended that FDA increase its efforts to inform health care professionals as to how to report problem information. In addition, to address the problem of severe underreporting from the hospitals, we recommended that FDA explore the possibility of establishing a voluntary problem-reporting network consisting of a representative sample of hospitals that would report to manufacturers. We have since pointed out that to ensure that the postmarket surveillance system achieves its "early warning" goal, it would be necessary to include virtually all hospitals in a mandatory problem-reporting program.

FDA generally agreed with the aims of our recommendations but expected that new reporting requirements being implemented by the agency at the end of 1984 would solve many of the problems we had identified. To learn whether this turned out to be the case, we did a followup review of this issue, which was published earlier this year.[5]

FDA began implementing the new Medical Device Reporting regulation in the latter part of 1984. Manufacturers of medical devices were then required to report to FDA whenever they became aware that a device was associated with the serious injury or death of a patient, or that the device malfunctioned in such a way that a recurrence of the malfunction could result in a serious injury or death. To handle the information produced by the new regulation, FDA established a system to process and analyze the data.

We found that the new regulation did greatly improve the flow of information to FDA. Indeed, the amount of information received by FDA about problems associated with medical devices increased more than seven-fold after the implementation of the Medical Device Reporting regulation. Prior to the regulation's implementation, FDA had received only about 2,500 problem reports annually through its voluntary reporting program. During the first three calendar years after implementation of the mandatory system, FDA received approximately 18,000 problem reports annual-

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[4] See Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting, GAO/PEMD-87-1 (Washington, D.C.: December 1986).

[5] See Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation, GAO/PEMD-89-10 (Washington, D.C.: February 1989).

ly, and there was a significant increase in the proportion of reported device problems associated with the death or serious injury of patients.

However, we found a number of problems with the new system, including the following:

First, even though the flow of information was improved, the real size of the problem was still unclear, and the degree of compliance with the Medical Device Reporting regulation's requirements could not be established. By FDA's count only a quarter of the manufacturers who were expected to file reports did so during any given year. However, under the present system, FDA has no way of distinguishing between manufacturers who truly have no reportable problems, those who are negligent in reporting, and those who are not aware that they need to file reports. (FDA's first check of a nonrandom sample of manufacturers showed that one-third of the establishments inspected for compliance with the Medical Device Reporting regulation did not even know there was a reporting requirement.)

Second, FDA's data processing system was not adequate to handle the volume of reports generated by the new reporting requirement. Although we found the information in the automated data base to be generally accurate; major delays were being experienced in getting reports into the system and analyzing them. For example, some portion of the processing or analysis was incomplete on more than 10,000 malfunction reports. Department of Health and Human Services [HHS] officials have stated that steps are being taken to correct these problems.

Finally, FDA's analysis of the data generated by the Medical Device Reporting regulation often did not produce definitive results. Specifically, over two-thirds of the reports received from 1985 through 1987 lacked a clearcut determination (for example, a recall, a voluntary action by the manufacturer, or even an indication that the information submitted by the manufacturer was insufficient to process the case). This situation may have resulted in part from the limited capacity of the FDA data processing facility to identify trends and anomalies associated with the occurrence of device problems. Again, HHS officials have reported that changes either under way or planned will improve the handling of device reports.

To address the problem of uncertain compliance with the reporting regulation, we made two recommendations to the secretary of HHS. First, we recommended a modification of the Medical Device Reporting regulation to require each firm that manufactures a medical device to submit an annual statement in one of two forms: (1) a declaration that no problem reports were filed because there were no reportable events, as defined by the regulation; or (2) a summary of how many reports were submitted for each type of event and a declaration that the manufacturer was aware of no other reportable events. FDA chose not to accept this recommendation on the grounds that it would provide no benefits while creating a burden for both the reporters and FDA. However, we believe that an annual statement would at least ensure that all manufacturers are aware of their obligations under the Medical Device Reporting regulation. This awareness on the part of medical device manufacturers to an indispensable first step toward achieving complete reporting.

Second, we recommended that FDA establish a program of Medical Device Reporting regulation compliance inspections that would permit generalization of the inspection results to the universe of device manufacturers—that is the selection of establishments for inspections on a sound statistical basis. To encourage greater use of the Medical Device Reporting regulation data base, we also recommended that FDA fully document their use of data in engaging in actions to correct device problems, especially by ensuring that such actions are recorded in the data base.

The last GAO reports I want to discuss today involve our examination of some of FDA's systems, procedures, and operations for engaging in remedial action once problems with medical devices have been identified.

When postmarket surveillance discloses problems with medical devices, several remedial actions are possible. However, the most far-reaching remedy is to take the device completely out of use—that is, recall it. In our current examination of device problems, we are looking at how the device recall process works and its results over the period 1983 through 1988.

Based on our reviews to date, we have been especially struck by the constraints under which FDA must operate. The agency has no authority under the Federal Food, Drug, and Cosmetic Act to order a manufacturer to recall a product. Thus, FDA may request a recall, but it has no statutory authority, without employing a court order, to impose or seek sanctions if its request is refused. The result of this situation is that the overwhelming majority of recalls are manufacturer-initiated with FDA oversight: FDA did not initiate any of the 1,635 product recalls that occurred during the period of our study. This means that manufacturers took the action when they believed recalls were warranted; and in almost half of the most

serious kinds of recalls, FDA learned of the recall from a source other than the manufacturer. However, this finding reveals no impropriety on anyone's part because there is no legal requirement for device manufacturers to notify the Agency.

Although FDA has surely made some progress since 1984, the overall impression created by its postmarket surveillance of medical devices remains one of inadequate information concerning the extent of existing device problems, and weaker analysis and use of the available information than the American public could reasonably expect of a national monitoring system.

In sum, the statutes that govern medical devices need some adjustment and the existing FDA systems for premarket review and postmarket surveillance both need improvement. The evidence is that the nation does not presently have a fully functioning process for ensuring the safety and effectiveness of medical devices. We are gratified that most of the problems we have pointed out and the recommendations we have made are being addressed in these hearings, as well as in H.R. 3095, as introduced by you, Mr. Chairman, and Mr. John Dingell, Chairman of the House Committee on Energy and Commerce, in the current session of this Congress.

That concludes my statement, Mr. Chairman. I will be happy to respond to any questions that you or the Members of the Subcommittee may have.

APPENDIX I.—SELECTED LIST OF U.S. GENERAL ACCOUNTING OFFICE REPORTS RELATED TO MEDICAL DEVICES

1. Medical Devices: Early warning of Problems re Hampered by Severe Underreporting, GAO/PEMD-87-1. Washington, D.C.: December 1986.
2. "Medical Devices: Early warning of Problems Is Hampered by Severe Underreporting," Statement of Eleanor Chelimsky, GAO/PEMD-87-4. Washington; D.C.: May 1987.
3. Medical Devices: FDA's Forecasts of Problem Reports and FTEs Under H.R. 4640, GAO/PEMD-88-30. Washington, D.C.: July 1988.
4. Medical Devices: FDA's 510(k) Operations Could Be Improved, GAO/PEMD-88-14. Washington, D.C.: August 1988.
5. Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation, GAO/PEMD-89-10. Washington, D.C.: February 1989.
6. Medical Device Recalls: An Overview and Analysis 1983-88, GAO/PEMD-89-15BR. Washington, D.C.: August 1989.
7. FDA Resources: Comprehensive Assessment of Staffing, Facilities, and Equipment Needed, GAO/HRD-89-142. Washington, D.C.: September 1989.
8. Medical Device Recalls: Examination of Selected Cases, GAO/PEMD-90-6. Washington, D.C.: October 1989.

STATEMENT OF ELEANOR CHELIMSKY

Ms. CHELIMSKY. Thank you.

I just wanted to make four points that will supplement what Mr. Bowsher has just said, two about the medical device reporting regulation and two about recalls.

First, FDA's system for processing problem reports is badly bogged down. When we went to evaluate it, we found about 53,000 problem reports had been received by FDA in the 3-year period between 1985 and 1987. But about 20,000 of them were still open and unresolved as of 1988. Also, many cases had been awaiting closure for as long as 2 years. We think the system is backlogged and in some trouble.

My second point is that we believe there is underreporting of problems of medical devices. We think so for four reasons. Only manufacturers are covered under the regulation, not hospitals or other users of medical devices. So we only know what those people are reporting to manufacturers that the manufacturers then report back to FDA.

The manufacturers who are reporting are only about one-quarter of the number that FDA had expected to report. During compliance

inspections, FDA found one-third of the establishments they visited weren't even aware of the mandatory regulation or their responsibilities under it. This was 3 years after the regulation had been adopted and after FDA had initiated an education effort with regard to manufacturers.

Finally, many reports of device-related deaths and injuries entirely unreported to FDA have been found in manufacturers' files and records. So we believe there is underreporting

With regard to recalls, all the action has been with the manufacturers. FDA cannot initiate a recall under the statute except with a court order, and manufacturers aren't required to inform FDA when they initiate one.

Even with the most serious type of recalls, class 1 recalls, manufacturers notified FDA in only 58 percent of the cases. So FDA is on the outside looking in and needs more statutory authority, not only with respect to its cognizance of recalls but also its own use of them.

My last point, even the best tested devices, those that had gone through clinical trials and premarket approval, were subject to recalls. There were 56 such cases. What this says is that even state-of-the-art testing at the front end cannot guarantee the safety and effectiveness of medical devices once they are in actual use.

That points up the critical importance of high quality postmarket surveillance. We believe FDA needs to be more proactive in fulfilling its mission. The real question is not how big a data burden can FDA conveniently handle, but rather what does the Agency have to know to protect the public health and safety?

Systems are needed that can deal with this; systems are needed, scientific samples need to be drawn so FDA can know how much compliance it is getting from manufacturers and users.

Confidence should be placed in an annual letter of certification by problem reporters rather than in educating them on their responsibilities. FDA should be able to initiate recall rather than having to wait for manufacturers to do so.

Thank you, Mr. Chairman. That concludes my summary.

[The prepared statement of Ms. Chelimsky follows:]

STATEMENT OF ELEANOR CHELIMSKY

Mr. Chairman and Members of the Subcommittee, it is a pleasure to be here today along with the Comptroller General of the United States to discuss GAO's studies on medical devices. The Comptroller General has given you an overview of all our work. I will concentrate on the Medical Device Reporting regulation and on medical device recalls. The Medical Device Reporting regulation is the principal means available for alerting the Food and Drug Administration [FDA] about problems associated with the use of medical devices. The recall is a way of taking action against these problem devices—by correcting them or removing them from the marketplace. The testimony I present today is based on the results of GAO's evaluations of FDA's first 3 years of implementing the Medical Device Reporting regulation (1985–88). Our overview and analysis of medical device recalls (1983 through 1988), and our examination of selected recall cases (also 1983 through 1988).[1]

[1] See Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation, GAO/PEMD–89–10 (Washington, D.C.: February 1989): Medical Device Recalls: An Overview and Analysis 1983–88, GAO/PEMD–89–15BR (Washington, D.C.: August 1939); and Medical Device Recalls: An Examination of Selected Cases, GAO/PEMD–90–6 (Washington, D.C.: October 1989).

Perhaps we can all agree that the introduction of beneficial but potentially dangerous technologies for health care involves a balancing of risks. An extreme approach on one side of the spectrum would be to introduce a technology only after all possible problems were identified and, in so doing, deny it to persons who might benefit from it. At the other extreme, a technology might be introduced as soon as minimal standards of safety and effectiveness had been satisfied but while doubts about the technology still existed. FDA reasonably aims at a middle ground between these extremes and attempts to use its premarket review and postmarket surveillance systems to balance the potential benefits of new health technologies against the associated public health risks.

As the Comptroller General stated this morning in his overview of our work on FDA's premarket review system for medical devices, our evaluations have revealed some serious flaws in that system.[2] More than a decade has passed since the 1976 amendments to the Federal Food, Drug and Cosmetic Act were promulgated with the goal of establishing a system that could provide reasonable assurances that devices introduced into the market place were safe and effective. But we found that many provisions of the amendments had only been partially implemented or not implemented at all. Among the effects of these implementation problems were the facts that FDA's premarket review process lacked some important risk-balancing components and that it did not function as well as it might to reduce the potential threat to the public health of unsafe and ineffective devices.

Perhaps these weaknesses in the premarket review system would not be viewed as such a threat if the public could be confident that FDA operated a high-quality and efficient postmarket surveillance system for medical devices. Such a system would logically include four activities: (1) gathering data about problems experienced with devices, (2) analyzing the data, (3) developing and implementing solutions to the problems, and (4) evaluating the successes of those solutions. These activities are needed to provide FDA with two critically important capabilities: to know which devices are creating what degree of risk to the public health, and to deal with those risks effectively.

Our most recent reviews of FDA's postmarket surveillance system examined mandatory problem-reporting by manufacturers and device recalls.[3] The findings from these evaluations continue to document serious vulnerabilities in that system.[4]

With regard to the Medical Device Reporting regulation, which generates data on device problems for FDA to analyze) we found that the implementation of the regulation produced a substantial increase in FDA's knowledge of device-related problems. The number of problems reported jumped from around 2,500 to some 18,000 annually. However, because only about one quarter of device manufacturers may in fact be reporting in any given year, this source still gives no indication of the real universe of device problems known to manufacturers, and supplies only part of the data FDA needs to estimate the size and status of device problems, assess their seriousness, search for new ones, or determine priorities for solution. Also, despite the increase in device-problem reports; the information supplied by manufacturers is still often lacking in the data needed to establish the cause of the problems reported. Moreover, we found that organizational and data processing problems further inhibit FDA's ability to analyze the information it receives.

With respect to device recalls, which are actions that can be taken to address serious device problems, we found critical deficiencies in both FDA's statutory authority and its own regulations and operating procedures. The major problem here is that the agency's ability to take problem-solving action is heavily dependent on the cooperation and goodwill of the manufacturers it is charged with regulating. Thus, the nation's principal guardian of the public health is, in many critical areas, reactive when it should be proactive.

Let me now turn to a more detailed description of these components of the postmarket surveillance system. I will begin with the Medical Device Reporting regulation and then will discuss medical device recalls.

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[2] See "Medical Devices: The Public Health at Risk," GAO/T-PEMD-90-2 (Washington, D.C.: November 1989).

[3] See appendix II for a discussion of the methodology used in these studies.

[4] Much of the information in this testimony is derived from our previous reports and thus represents the state of medical device regulation in 1988; at the time the studies were completed. In response to our reports, FDA has described a number of initiatives addressing many of the issues raised by our findings that were either undertaken after we had completed our data collection or were planned for the near future. However, we have not conducted a complete and formal followup review of the agency's actions on the issues covered in our reports.

This regulation was promulgated on December 13, 1984. It required device manufacturers to report to FDA whenever they became aware that one of their devices had been associated with the serious injury or death of a patient; or had malfunctioned in such a way that a recurrence of the malfunction could result in a serious injury or death. To implement the regulation, FDA established a system to process and analyze the device-problem reports, and procedures to monitor manufacturers' compliance with the provisions of the regulation. Our evaluation dealt essentially with the implementation of the regulation, and with the characteristics and usefulness of the information received by FDA.

Nearly 53,000 problems, involving 1,059 separate devices, were reported to FDA during the first 3 years of the regulation's operation, and overall these problems were more serious than those reported to FDA through the prior voluntary problem-reporting program. Nearly 90 percent of the voluntary problem reports had been related to device malfunctions, and only about 1 percent to the death of a patient. Under the new regulation, slightly more than half the reported problems were associated with patient injury, and about 1,550 problem reports, or 3 percent, were associated with patient death.

Problems were concentrated in relatively few medical specialties, and in relatively few devices within those specialties. For example, over 75 percent of all reported deaths were related to devices in the anesthesiology and cardiovascular medical specialties. And within the 19 FDA-designated medical specialties, 10 devices accounted for 63 percent of the problem-reports Cardiac pacemakers and pacemaker electrodes accounted for over one-third.

With regard to the scope of the information potentially available to FDA from the Medical Device Reporting regulation, it is important to remember that the regulation addresses only one link in the chain of information associated with device problems—the link connecting device manufacturers to FDA.[5] It was not the intent of the regulation to address the other major links in the chain—those connecting hospitals to manufacturers, hospitals to independent distributors, independent distributors to manufacturers, and hospitals to FDA. What this means is that the information contained in the Medical Device Reporting data base will not reflect the problems experienced by users in hospitals and elsewhere, unless those problems have been reported to the manufacturer, who then in turn reports them to FDA. So the information potentially available to FDA through the regulation is, at best, limited to those problems manufacturers are aware of.

But even this information that flows from manufacturers to FDA is itself limited by the degree of their compliance with the regulation. We reviewed the evidence on such compliance and found, first, that problem-reporting was concentrated among a relatively small number of firms. At most, only about one-quarter of the number of device manufacturers originally expected by FDA to reports, have in fact reported during any year. When we compared the number of manufacturers who have actually reported a device problem to the number of potential reporting manufacturers (a number suggested by the most conservative of several estimates), at least some degree of underreporting or noncompliance on their part seemed clear; how much, we cannot specify. That is, because FDA could not provide us with the total number of manufacturers subject to the problem-reporting requirements of the regulation, we could not estimate the degree of their compliance.

We also found some instances of "overreporting" by manufacturers, which were apparently caused by too much zeal or a lack of understanding of the reporting requirements. In one case, a manufacturer was reporting all routine service requests made by device users. Unfortunately, such overreporting tends to clog the information system and use up scarce resources without bringing with it any potential for significant risk reduction.

But if overreporting is wasteful and unhelpful, it is underreporting which constitutes the greater threat to FDA's ability to find out about device problems, analyze them, and act on them. We found one case in which a device manufacturer accumulated information—but did not report it to FDA—concerning a large number of incidents in which one model of the product was associated with patient deaths as well as injuries and malfunctions. Because of this manufacturer's interpretation of what the requirements of the Medical Device Reporting regulation are, no reports had

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[5] See Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting; GAO/PEMD-87-1 (Washington, D.C.: December 1986).

been submitted to FDA on the majority of these complaints, including 51 involving the deaths of patients, most of whom were infants.[6]

It was only through a routine FDA compliance inspection of the manufacturer's records, including a review of the previous 14 months of the files, that FDA inspectors found 10 unreported complaints that they judged should have been reported under the regulation requirements. FDA and the manufacturer then engaged in a 13-month-long negotiation to distinguish what was reportable under the regulation from what was not. The agreement finally reached between FDA and the manufacturer resulted in the manufacturer's conceding that 6 of the 10 complaints should have been reported. This failure on the part of the manufacturer to report these 6 complaints constituted noncompliance with the reporting regulation. Most important of all perhaps, in terms of what this case illustrates about manufacturers' potential underreporting, is that these events took place more than 3 years after the regulation had been promulgated and FDA had carried out an educational program on the reporting requirements for manufacturers. But until the agreement was reached, at least with respect to this single manufacturer, it is clear that FDA was not receiving the information expected under the regulation.

We cannot estimate the scope of this type of problem (in part, because FDA has not given us a list of the manufacturers covered by the regulation). But some findings suggest that the compliance problem just described may not be an isolated incident. FDA has tried to assess the degree to which manufacturers are conforming to the requirements of the Medical Device Reporting regulation through a series of record inspections. FDA's judgmental sample was composed of manufacturers the agency believed would be most likely not to be in compliance. These compliance inspections showed that about one third of the manufacturers visited were unaware of the existence of the reporting requirements, and uncovered records of a number of deaths and serious injuries—associated with pacemaker leads, intraaortic balloon catheters, and other devices—that had not been reported to FDA.

Again, because we have no universe of manufacturers covered under the regulation and hence cannot draw a scientific sample to analyze the representativeness of what FDA has found, these FDA results cannot be validly generalized to the industry's state of compliance as a whole.

We told FDA officials that they should not continue to use a judgmental sample selection process for scheduling Medical Device Reporting regulation compliance inspections, even if this process eventually were to lead—every 4 years or so—to a full census of manufacturers, as the agency claimed it would. Such a process might have been justified at the beginning of the program—when the primary goal of compliance inspections was to educate manufacturers—in order to induce compliance with reporting requirements. But when it becomes necessary, as it is now, to develop unbiased estimates of just how extensive the problems of noncompliance may be and how many device problems may have gone unreported; then to use a judgmental sample is to defeat the goal, because data from such a sample cannot be validly generalized to the population of device manufacturers.

We also recommended that FDA address the compliance question by requiring manufacturers to submit a single annual letter—which, for the majority of firms, would merely assert that they had nothing to report and, for the remainder only that the stated number of reports submitted covered all reportable problems of which the manufacturer had become aware. We believe such an annual letter would do five things to reinforce FDA's capabilities in this situation: ensure manufacturers' awareness of the regulation and their responsibilities under it; establish a better basis for estimating the real incidence of device problems known to manufacturers; provide an annual data base for accurately gauging the number of manufacturers who have reported during the year (at present, nonreporters who have not received information about reportable events cannot be distinguished from those who don't know about or understand their reporting requirements or are otherwise in noncompliance); provide data that could confirm or alter FDA's conclusion that it

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[6] Problems to be reported under the mandatory Medical Device Reporting requirement are not limited to events in which there was a confirmed causal connection between a device and an adverse experience. They include many events in which there is an association between a device and the death or serious injury of a patient. For example, defibrillation is successful in only a small percentage of patients who experience ventricular fibrillation, even when the defibrillator works properly. Therefore, even when it does not malfunction; if a manufacturer receives information that "reasonably suggests" that the use of a defibrillator may have caused or contributed to a death or serious injury through, for example, a failure to follow instructions, the manufacturer is obligated to report the incident in a Medical Device Reporting regulation death or serious injury report.

is normal for only a limited number of manufacturers to report problems under the regulation; and allow FDA to check the number of each type of reportable event a manufacturer claims to have submitted during a year against the reports actually in its data base, and to investigate discrepancies that suggest that some reports may have been "lost" or delayed in the processing system.

Now let me turn to the organizational structures and procedures FDA established to process and analyze the reports generated by the Medical Device Reporting regulation.[7]

Although FDA first proposed a mandatory adverse-experience reporting system in 1980, we found little evidence of effective overall system development and planning when we conducted our review 8 years later. Instead, we saw a system ill-equipped to handle the increase in the volume and types of reports expected to be generated by the Medical Device Reporting regulation. And indeed, when the expected problem-reports were submitted, the size of the increase and the complex nature of FDA's work flow contributed to a constant report processing backlog. In addition, we found some inefficiencies in analyzing and taking action on problem reports. For example, for nearly one-third of the reports that FDA received, dispositions had not been made and cases were not closed, even though many of these reports had been submitted more than 2 years earlier; some critical information had not been entered into the problem-reports data base in a timely fashion, including reports both of deaths and serious injuries, and records of actions that FDA had taken in response to problem reports; and finally, formal written procedures for report analysis were lacking, and there was a reliance on informal training for report analysts in the use of the available automated data processing equipment and software.

Thus, final dispositions were not made in about one third of all the mandatory problem reports received by FDA between 1985 and 1987, and this also means that they were not given causal evaluations. Further, for the two thirds of the reports that were evaluated, the cause of the device problem was tentatively identified in only half. This situation arises because FDA primarily relies on the manufacturer's determination of cause, as indicated on the submitted problem report. If the manufacturer has not indicated a cause—which is the case more often than not—there is generally not enough information in the problem report for FDA alone to determine the cause.

In addition, we identified several internal problems with the automated data processing facilities that severely limited their capacity to support FDA's risk assessment activities. The potentially most troublesome problem was that although there were several data bases at FDA that related to postmarket surveillance, they were not integrated into a single functional system that was easily accessible or complete enough for adequate problem-report analysis. In consequence, there were gaps in the information available to analysts and redundancy among the several different data bases used.

In sum, with the procedures we found in place, FDA can record and retrieve information about individual problem reports. But because of the reporting, analytical and efficiency problems discussed above, the agency cannot yet easily identify generic issues or provide systematic, quantitative analysis of problem-reporting patterns based on statistical trends over time.

The last aspects of the postmarket surveillance system I would like to discuss today are the use of problem-report data in solving device problems and, especially, the use of medical device recalls as postmarket surveillance tools.

The purpose of the medical device risk assessment activities that I have just described—data gathering, processing, and analysis—is to provide an empirical basis for the development and implementation of problem solutions. For medical devices, this activity includes using the report data as a source of "early warning" about device problems and acting on that information via recalls and other regulatory actions.

Although other information supplied by FDA indicated that report data may have helped FDA in dealing with device problems in some instances (including a few device recalls initiated by manufacturers,; changes in the design of one type of device, and an educational program for hemodialysis users), the automated data base we reviewed documented very little use of the report data by FDA.

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[7] FDA contracted with U.S. Pharmacopeia [USP] to receive and enter problem reports of deaths and serious injuries into an automated data base. Under this contract, reports of device malfunctions are reported directly to FDA, then analyzed and subsequently forwarded to USP for computer entry. The analysis and disposition of problem reports are primarily carried out by a team of 12 analysts in FDA's Center for Devices and Radiological Health's [CDRH] office of compliance.

The data we analyzed showed only three instances of traditional FDA regulatory actions—such as device seizures and Notice of Adverse Findings letters to manufacturers—that could be linked directly to the problem-report data.

Over the last year, we have begun to study recalls as the principal mechanism available to FDA and device manufacturers to correct problems that occur after a device is marketed. Our first two studies of medical device recalls focused on the nature and scope of recalls, while our ongoing work focuses more specifically on evaluating the effectiveness of recalls as a problem-solving tool. In a future report) we plan to examine how the recall process actually operates with respect to specific devices and, if necessary, to suggest ways to improve the overall process.

A medical device "recall" is more than the removal from the market of a particular product. It can also include the correction of labeling or of promotional materials that FDA considers to be in violation of the laws it administers. FDA divides recalls into three classes based on its evaluation of the relative degree of health hazard the products present.[8] In the most-serious class (class I), there is a strong likelihood that the use of or exposure to the product will cause serious adverse health consequences or death. In the medium-serious class (class II), the use of or exposure to the product may cause temporary or medically reversible adverse health consequences, but the probability of serious adverse health consequences is considered remote. In the least-serious class (class III), the use of or exposure to the product is not likely to cause adverse health consequences.

Our analysis of medical device recalls was based on a total of 1,635 recalls. Medium-serious recalls were the most frequent at 1,026, or 63 percent; these were followed by 561, or 34 percent, least-serious recalls; and 48, or 3 percent, most-serious recalls.

The devices that were recalled ranged from high-risk, implantable, life-supporting devices (such as replacement heart valves) through medium-risk devices (such as tanning booths) to low-risk devices (such as dental irrigation syringes).

Devices from every medical practice specialty area were subjected to at least one recall. However, recalls in 42 percent (8 of 19) of the medical practice specialties accounted for 80 percent of all recalls. Devices from two specialties—cardiovascular and anesthesiology devices—accounted for slightly more than one-quarter of all the recalls.

FDA assigns causes of problems leading to recalls to one of nine classes by relying on narrative statements provided by the manufacturer.[9] According to this categorization of device problems, design and production problems were identified as the causes of nearly three-fourths of all recalls. We found that the most frequent cause of recall was some element of product design, which accounted for 715, or 44 percent of all recalls. Problems with production controls accounted for 460, or 28 percent, of the recalls.

We also found that 74 percent, a disproportionate share of all recalls and the majority of the most serious recalls, were related to medium-risk devices for which mandated performance standards have not been developed by FDA. (The Comptroller General has discussed the importance we attach to this omission.) [10]

Our analysis confirmed the anticipated relationship between device's risk classification and its recall classification. High-risk devices were more likely to be among the most serious recalls, while low-risk devices were more likely to be among the least serious recalls.

FDA and the Congress envisioned that one of the principal benefits of the reporting requirements of the Medical Device Reporting regulation would be their function as an "early warning" of device problems. And, since the regulation has been in effect, 274 medical device recalls, or 22 percent of all recalls, have had a problem report associated with them.[11] There also was a positive relationship between the

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[8] It is important to note that the potential degree of health risk associated with recall classes is designated, by FDA, in a descending order from class I to class III (that is, a class I recall involves the most serious risk), and the potential risk associated with device classes is designated in an ascending order from class 1 to class 3 (that is, a class 1 device is low risk) . Therefore, classes I and 1 have opposite meanings for devices and recall classes. To avoid confusion, in this testimony, we refer to class I, II, and III recalls as "most serious," "medium serious," and "least serious," respectively.

[9] FDA's categories of the causes of device problems that lead to recalls are as follows: (1) design, (2) production control, (3) component control, (4) expiration dating and Radiation Control for Health and Safety Action violation, (5) change control, (6) training, (7) misbranding, (8) no premarket approval, and (9) other.

[10] See "Medical Devices: The Public Health at Risk," GAO–T/PEMD–90–2 (Washington, D.C.: November 1989).

[11] Our analysis accounts for the 1,245 recalls made between fiscal year 1985 and fiscal year 1988, the years in which the Medical Device Reporting regulation was in effect.

recall class and the existence of a problem report—that is, the more serious the level of the recall, the more likely it is that a report was associated with the device problem. Nonetheless, we found that only 16, or 52 percent, of the most-serious recalls had reports associated with them at the time FDA conducted a risk assessment in connection with the recall. Thus, FDA became aware of the great majority of device problems associated with a recall in some other way than through mandatory problem reports. This suggests that the reports have not served as an effective early warning of device problems serious enough to warrant a recall.

This suggestion is consistent with our finding that although FDA did become aware of the majority of most-serious recalls before they were completed, in 44 percent of those cases the agency learned of the recall only after it had been initiated by the manufacturer.[12] Some corrective actions by manufacturers—serious enough to be labelled most-serious recalls—did remain unknown to FDA until it learned of them during an inspection or was informed by a device user or one of the manufacturer's competitors. But since there is no statutory requirement that device manufacturers notify FDA of recalls, it is not surprising that FDA's awareness of them should be incomplete.

Our analysis showed that manufacturers notified FDA of class I recalls (that is, the most serious ones) in 58 percent of the cases; in 43 percent of the cases FDA found out about the existence of the recall from some other source (including, in 25 percent of the cases, its own inspection).

We also looked specifically at the incidence of recalls for devices that had gone through the premarket approval route to market. These recalls are particularly noteworthy because the most stringent statutory requirements to ensure safety and effectiveness—including the performance of well-controlled studies or the production of other scientific evidence—are reserved for devices that require premarket approval. However, we found 56 recalls of premarket-approved devices over a period of 6 years, which is equivalent to 4 percent of total recalls. This roughly approximates the proportion of devices that had entered the market in the first place through the premarket-approval route (6 percent). Premarket-approved devices were also more likely to be associated with the most-serious class of recall than either of the other two classes of recalls. These findings underscore the critical nature of FDA's postmarket surveillance of all devices, even those subject to the most thorough effort to identify and solve their potential safety problems before they are marketed.

We believe that, at a minimum, FDA's postmarket surveillance system should be able to rapidly and completely identify serious problems experienced with medical devices (such as those described in the Medical Device Reporting regulations). We also believe the agency should have the capability to act quickly to resolve problems once they have been identified. Neither of these capabilities currently exists in adequate form at FDA.

The evidence we gathered in our evaluation of FDA's implementation of the Medical Device Reporting regulation and medical device recalls shows that both of these elements of the postmarket surveillance system are vulnerable in ways that inhibit the system's capacity to either provide early warning about device problems or allow the agency to act expeditiously on those problems.

Instead, we found that: the system FDA has established to process and analyze the problem reports is not adequate to handle the volume and types of reports received; the degree of manufacturers' compliance with the regulation cannot be accurately determined; the reporting requirement is not serving its expected purpose of providing the agency with early warning of device problems; and because of the existing statutes, FDA is limited in its ability to find out about manufacturers' recalls or initiate its own corrective actions for device problems.

We recognize that during the 1980's added demands have been placed on FDA as a result of its having to deal with such problems as the AIDS epidemic, cases of product tampering, and other issues. However, we believe that at least some of the vulnerabilities we have identified with regard to FDA's postmarket surveillance system are not resource-dependent. Much can be accomplished through improved monitoring and enforcement actions in conjunction with mandatory reporting and changes in the Federal Food, Drug, and Cosmetic Act to increase FDA's recall authority. The requirement for an annual form letter submitted by device manufacturers, certifying their compliance with the reporting regulation and documenting the use of problem-report data, is neither costly nor burdensome for either FDA or manufacturers. The statistical sampling strategy we have recommended would produce

[12] Information on the time of FDA's notification was missing in 7, or 15 percent, of the cases. These percentages are based on 41 cases for which the data were available.

generalizable results sooner, more often, and at lower cost than the FDA proposed census. And finally, changes in the Federal Food, Drug, and Cosmetic Act would allow FDA to take prompt action against medical devices that pose unreasonable risk of substantial harm to the public health. The changes should include the requirement that manufacturers report to FDA all recalls and repairs done to eliminate health risks or violations of the law. We expect to make additional recommendations after we complete our evaluation of the effectiveness of the recall mechanism.

That concludes my statement Mr. Chairman. I will be happy to respond to any question that you or members of the subcommittee may have.

Appendix I.—Selected List of U.S. General Accounting Office Reports Related To Medical Devices

1. Medical Devices: Early warning of Problems re Hampered by Severe Underreporting, GAO/PEMD-87-1. Washington, D.C.: December 1986.
2. "Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting," Statement of Eleanor Chelimsky, GAO/T-pPEMD-87-4. Washington; D.C., May 1987.
3. Medical Devices: FDA's Forecasts of Problem Reports and FTE's Under H.R. 4640, GAO/PEMD-88-30. Washington, D.C.: July 1988.
4. Medical Devices: FDA's 510(k) Operations Could Be Improved, GAO/PEMD-88-14. Washington, D.C.: August 1988.
5. Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation, GAO/PEMD-89-10. Washington, D.C.: February 1989.
6. Medical Device Recalls: An Overview and Analysis 1983-88, GAO/PEMD-89-15BR. Washington, D.C.: August 1989.
7. FDA Resources: Comprehensive Assessment of Staffing, Facilities, and Equipment Needed, GAO/HRD-89-142. Washington, D.C.: September 1989.
8. Medical Device Recalls: Examination of Selected Cases, GAO/PEMD-90-6. Washington, D.C.: October 1989.

Appendix II.—Methodology

Our fieldwork was conducted from October 1987 through June 198 in accordance with generally accepted government auditing standards. Our review of the implementation of the Medical Device Reporting regulation and of medical device recalls required different kinds of information from many sources. To understand the congressional intent and historical background of each element, we reviewed the legislative histories, prior studies of the implementation of the regulation, FDA policy and guideline statements; FDA procedure manuals, and other published articles related to mandatory adverse experience reporting and device recalls. We also obtained an official chart of the problem reports processing and analysis work flow and recall processes, and used this information as a basis for structured interviews focused on the day-to-day operations of these systems. We interviewed FDA officials, program managers, inspectors, and other staff in order to clarify, supplement, and confirm the documentary evidence.

FDA provided a computer tape containing the problem reports data base for the period January 1985 through December 1987 and another tape of the recall data base for fiscal years 1983 through 1988. We used these tapes to review the accuracy and completeness of the data bases, to tabulate summary statistics, to analyze patterns and characteristics, and to evaluate FDA's actions in response to medical device problems.

We also assembled a distinguished panel of medical device experts affiliated with academic, consumer research, industry, health care provider, and other institutions for advice and consultation. (See appendix III for a list of our panel members.)

Appendix III.—Members of Medical Devices Expert Panel

Lee Bancroft, Beth Israel Hospital, Department of Anesthesiology, 330 Brookline Avenue, Boston, Mass.

Edward Basile, Esq., King and Spaulding, 1730 Pennsylvania Avenue, Washington, D.C.

William Beck, M.D., President Emeritus, Donald Guthrie Foundation forMedical Research, Sayre, Pa.

Robert Mosenkis, Director, Center for Information on Technology for Health Care, Plymouth Meeting, Pa.

Charles Rawlings, Ph.D., Professor, Department of Electrical Engineering, Southern Illinois University, Carbondale, Ill.

Sidney Wolfe, M.D., Director, Public Citizen, Health Research Group, Washington, D.C.

Mr. WAXMAN. Thank you for your testimony. You have given us a very discouraging picture of what is going on at Food and Drug Administration with respect to these medical devices. If, you told us, there is a problem when the devices go on the market, FDA doesn't know whether they are safe, let alone effective.

Once they are on the market, there are problems with respect to whether FDA ever learns about the device that is offering a threat to people's health. And then even when they know about it, there doesn't seem to be actions being taken to take these devices off the markets so the public is protected.

Mr. Bowsher, you have worked with all sorts of regulatory agencies in your capacity as the head of the General Accounting Office. How does the standards or actions of the FDA in the medical device area compare with what other regulatory agencies are doing with respect to their regulatory assignments?

How would you characterize this?

Mr. BOWSHER. It is one of the poorest, I would think. In other words, not that we don't have problems in some of the other regulatory agencies. I think in this past year we have been reporting on problems with the nuclear weapons plant where it is obvious the reporting is limited.

Even when you get reports, the Government agencies are not able to handle the volume of reports or take action on it. I see this as a very serious situation. We have other problems in the Government that are not too dissimilar, unfortunately.

Mr. WAXMAN. The public has to rely on these medical devices. Some, like pacemakers, are inserted and they are relying on them to keep their hearts beating at the regular pace.

These monitors for babies we will hear more about later, you wrote about in your report that they are supposed to detect if a baby is going to be stricken by the sudden infant death syndrome. We have lifesaving and also live-threatening devices. Can you tell us, as you reviewed the actions of the FDA, that the public can feel they are being adequately protected by the FDA policing the devices to be sure they are safe and effective?

Mr. BOWSHER. No. I think it is very clear here, as we have shown in our reports, that there is very little testing going on. Even when problems are reported, the problems are not dealt with in many cases.

So I think you have a very poor situation here.

Mr. WAXMAN. Let me turn to the premarket approval process. FDA is supposed to look at a device and decide whether it is safe or effective. Particularly if that device offers a substantial risk, they are supposed to do a review of it before it goes on the market.

There is a provision in the law that allows FDA to look at devices that are already on the market, and if they say the new device is substantially the same as the old device; that they can approve it without reviewing it. You say 94 percent of all medical devices reaching the market do so through this what is called the section 510(k) route which is the loophole grandfathering them in.

That means there is no direct evidence of safety or effectiveness required, just support of the manufacturer's claim of equivalence.

The concern is the device only has to be substantially equivalent to that device that was available prior to 1976. We all know time flies, especially with respect to medical technology.

Does it make sense for us to continue to use a pre-1976 device as a standard for today? Is that a way to determine whether to actually, it is actually safe?

Mr. BOWSHER. I think that was a method adopted to try to not get overwhelmed by the number that would have to be tested. I think as the years go on now, it is more and more a very dubious procedure because we are just about to enter 1990 here. That is about 14 years from 1976.

So we are relying more and more on devices that have old technology. As you point out, the technology is moving very, very fast here. So I think this is an issue that should be looked at very, very carefully. I think to continue to rely on a mechanism that has 94 percent of the devices going through untested, is a very serious situation that ought to be given a lot of consideration.

Mr. WAXMAN. Ninety-four percent of these devices are going on the market without having been clearly scrutinized by FDA. Once these devices are being used, does FDA learn about the problems? What I want to know from you is does FDA know what it needs to know to assure the public that it knows about serious problems with medical devices?

Mr. BOWSHER. No. That is the thing that worries us about the postmarket situation. That is that we don't believe we are getting the FDA concentrating on the major problems here. In many cases we are not getting them reported.

As we point out, since 1984 we have had better reporting. But the ability of FDA to handle that reporting has been poor.

So, I think you have a situation where you basically are relying upon the manufacturers in the way the system is working today.

Mr. WAXMAN. FDA is basically relying on the manufacturers to tell them about problems. I believe that the law now mandates that the manufacturers do tell the FDA about problems they learn about their devices that offer threat of death or serious injury or malfunctioning.

Are the manufacturers doing what they should be doing to report to FDA?

Mr. BOWSHER. When we did our followup review, about one-fourth of them are. But what was even more disturbing was the group that didn't even know, or at least they said weren't aware, they were supposed to report.

Obviously, the educational or outreach program has not taken place. Therefore, you do not have the manufacturers properly reporting to FDA.

Mr. WAXMAN. Now we have got a device that offers a problem. We are pretty much relying on the manufacturers to recall the devices if there is a problem. You point out that there were 1,635 recalls during the period you studied and that everyone was initiated by the manufacturer.

Did FDA initiate any recalls?

Mr. BOWSHER. No, none.

Mr. WAXMAN. FDA did not initiate any recalls of the 1,635 recalls that were implemented. They were implemented solely by the manufacturers.

If there are that many recalls, is there a problem? Manufacturers maybe are doing a good job?

Maybe it doesn't make a difference whether FDA is involved. How would you respond to that?

Mr. BOWSHER. You don't know the extent of the problem until people run into problems here, some very serious, as the evidence has been brought in. But you are depending on the informal system of the medical people reporting to the manufacturer and the manufacturer taking action. Needless to say, there are incentives for the manufacturer not to have bad devices out there.

They are in many cases, I am sure, taking action. But on an overall basis, you really don't know what the facts are. The Government doesn't know.

That is the purpose of the FDA. As regulators, they are supposed to know what is going on.

Mr. WAXMAN. Ms. Chelimsky, you mentioned four elements of postmarketing surveillance systems that you identified. Collecting data are problems, analyzing the data, developing and implementing solutions and evaluating the success of these solutions. What is your opinion of how well FDA is succeeding with each step?

Ms. CHELIMSKY. Overall, I would say not very well. You have already heard me tell you about the problems of the backlog system that they have. In other words, we have seen better data coming in, but we don't know what that data represents in terms of, you know, whether this is a jack or a deuce. Fifty-three thousand over 3 years, that sounds like a lot, but if only one quarter of the manufacturers that should be reporting are reporting, maybe the issue is four times as big, maybe it is not.

But we need to know that, and FDA doesn't know that.

Also, I think for analysis, there are a great many problems. There are great difficulties in going across the five systems that FDA has for developing data. You have the MDR system, the problem reporting system, you have earlier systems like the section 510(k) process, and you have premarket approval. In order to understand what is happening with a device, you need to be able to take a look at what happens at the beginning of the process, whether it has been tested, what happened after it was tested, what were the problems that were found and what action was taken. And FDA at the present time because of hardware incompatibilities, because of a whole variety of software packages they use, is in a poor position to be able to do that. Generic analysis, trend analysis needs to be done. They need to move from tracking an individual case to taking a look at types of devices that are problems.

They can't do that at the present time. They are not doing it.

With regard to taking action, I think that is the part that troubles me the most. It seems to me that FDA does have some mechanisms available to it.

It can ban a device, for example, if it has to. I believe it has banned just one device as of 1984, synthetic fibers implanted into the scalp. It can issue letters of notification of adverse findings. It

can issue regulatory letters. There are things that it can do short of recall, but it hasn't done much. So, you know, the issue is, is it a lack of capacity, is it a lack of statutory capability or is it a question of being reactive as opposed to being proactive in a situation where something needs to be done?

Mr. WAXMAN. What is your answer to that question? Is the problem at FDA that they don't have the capacity? Is the problem they don't have a clear statutory mandate or lack of will?

Ms. CHELIMSKY. I think it is both, but I am concerned about whether or not that is going to make an enormous difference.

I would point out one thing: for the 1,635 recalls that we talked about earlier—that FDA did not, in fact, initiate—they were instrumental in getting a lot of them done. What they do do is informally influence the manufacturers. They say to them, "We have seen these reports. It is time to do something. They do those things, so they have tried. I don't think it is hopeless.

With regard to evaluation, we are going to be doing one. I can't tell you at this point about the success of the system.

Mr. WAXMAN. You did the followup on infant deaths from these monitors. As I understood the report you submitted to us, it was that FDA at first didn't even know about the problems with the monitors. The manufacturers didn't tell them. When the FDA was informed, they didn't appear to be insisting on recalls.

They seemed to be bending over backwards to let the manufacturer do whatever they wanted to do. Tell us what you found there with FDA's actions.

Ms. CHELIMSKY. Well, first of all, it seems to me that it was a long time between the implementation of the device law and their inspection of this manufacturer's plant.

Something like 3 years took place before they went out and did an inspection. Then after that when irregularities were found, in other words, reportable problems were found with the monitor, it took some 6 months before they then sent out a notification letter and then another close to 8 months for negotiations about which problems were in fact reportable.

These are to some degree legal issues. It is very hard to say that FDA was dragging its feet. There was some work that had to be done. There were negotiations because the company did say that they didn't think that some of the problems were reportable.

So that had to be cleared up. The final thing was that 6 out of the 10 were considered to be reportable, as I remember.

Mr. WAXMAN. Reportable meaning FDA——

Ms. CHELIMSKY. That FDA should have had the reports under the regulations, and the company did not report them.

Mr. WAXMAN. Dr. Rowland.

Mr. ROWLAND. Thank you, Mr. Chairman. It is apparent that the most market surveillance system is badly flawed and needs major surgery in order to get it into line the way it should be. But, I want to focus a little bit on the premarketing evaluation.

Can you make a brief comparison of the way that the system for new drugs works compared to the way that the system for medical devices works?

Ms. CHELIMSKY. I can't.

Mr. BOWSHER. We have not done that work.

Mr. ROWLAND. It seems to me that the system for medical devices is much looser than that for new drugs. It seems to me that if we were to give more attention to the premarketing evaluation of medical devices perhaps we won't have nearly as much trouble with medical devices after they have been put in use and for the problem that we are encountering with them in death and injuries to patients.

Could you comment on that, the premarketing evaluation?

Mr. BOWSHER. I think the emphasis on premarketing does make sense. What you are trying to do is to avoid the problems. There is no question that FDA is limited on resources in many areas. We have just done a special study on that. But we think that they have to come up with a strategic plan as how best to use their resources before the Congress should appropriate more.

But I think at some point in time you have got to have an adequate pretesting, premarket testing here to avoid some of the problems. It is much better to put a lot of emphasis there than on the postmarket, if you can do it.

I think there is no reason why they shouldn't be able to do a much better job than they are doing now.

They have found this loophole, as the chairman refers to it. It is very legal, of course, to say that it is equivalent to the pre-1976 device. But I think what you have got to do here is figure out what devices should be reviewed, set some standards and get the job done, and I think we can save quite a few of these bad situations from happening.

Mr. ROWLAND. I am hearing you say that FDA does not have a strategic long-range plan in premarketing evaluation?

That if it were in place better, then we would not be having the problem that, in fact, maybe while additional money would help, that does not rid of the problem?

Mr. BOWSHER. In fact. I think as part of their overall strategy for the whole organization, they need these kinds of strategies in the key areas, and this is one of the key areas, medical device area.

Then I think you can look at the staffing problem much better and decide whether the Congress, the American people should be making a greater investment in this area.

I suspect if you had the right plan, the people would be more than willing to make the investment.

Mr. ROWLAND. Do you have an idea about what the right plan ought to be?

Mr. BOWSHER. I think it would be better for them to come up with their plan and for somebody like ourselves to review it.

Mr. ROWLAND. Let me turn to the problems encountered with medical devices when they don't work as they should.

Of course, there is recourse in the courts for people who are injured.

Can you comment on that, how often this is taking place and how it is working insofar as dealing with these problems?

Ms. CHELIMSKY. We have a great deal of difficulty in being able to establish that. In the problem-reporting system that they have, the FDA very often says with regard to a particular device, "patient death, one or more." They don't say how many. There is no way to be able to figure out for each device and for each number of

problem reports, how many patient deaths are involved without doing an inspection and going into the files of the manufacturer and seeing in fact how many reports are there.

I would add just one thing to the point about devices and drugs that you were talking about a minute ago. I think one important difference with devices is that you have the intermediary of the person who is using the device when it gets on to the market.

This is one of the real things that vitiates the premarket system, even when it is much better, and there is no question it could be vastly improved. But the difficulty is that it is very hard to predict how much education everyone who uses that device needs to have.

So there can be problems with a device, but also problems with the knowledge of the person using it. It is not quite the same with drugs.

Mr. ROWLAND. I guess it is like liability. Certainly you would not want to take a lawn mower that is being used to mow your lawn and try to cut a hedge with it. I am sure there is some responsibility there.

One other thing I would like to ask, while ignorance of the law is no excuse, do you have a feeling as to how much of the manufacturers may actually be ignorant of the law insofar as their reporting is concerned and responsibility?

Mr. BOWSHER. Our followup review here indicated that one-third of the manufacturers inspected by FDA claimed that they were unaware of their reporting requirements.

Mr. ROWLAND. Why would they be unaware of that, do you suppose?

Mr. BOWSHER. I think it is a manner of education and outreach. In other words, I think when the Government puts in new reporting requirements, if we don't have a proper education and outreach program, then the word doesn't get out. That has been our experience in many areas.

I think that is what is necessary. For us to come along 3 and 4 years later and find that many people are unaware of their requirements, I think you have a serious problem.

Mr. ROWLAND. Is that the responsibility of the FDA to make that known?

Mr. BOWSHER. To a great extent I think it is.

Mr. ROWLAND. Or else does that responsibility lie——

Mr. BOWSHER. With some of your professional organizations and some of the manufacturers.

You can't, of course, take some of the responsibility away from the manufacturers themselves. They are supposed to keep current on what their reporting requirements are.

Mr. ROWLAND. Thank you.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Dr. Rowland.

Mr. Nielson.

Mr. NIELSON. Thank you, Mr. Chairman.

I am sorry I wasn't here to hear some of the testimony.

Let me ask you a question about the apnea monitor. That is not known to be reliable in measuring the respirator for infants.

It is usually operated by a lay person and not an expert. Yet, that is all we have in some cases. How do you weigh the benefits and risks of this particular one?

Is it worth the risk because it is not 100-percent reliable and because it is usually operated by lay people?

Ms. CHELIMSKY. Well, as you say, it is a difficult problem. I think this issue boils down to who needs to know what. We know that the monitor has problems and we have known that for some time.

There are problems of what they call false negatives. That is the monitor picks up other noises in the room.

What happens is it doesn't realize—being a machine, it doesn't realize anything—that the baby has stopped breathing. But we have known this for some time.

I think one of the things that really strikes you about this whole business is that the manufacturer didn't think it was necessary to let parents know that there were these problems.

So that it seems to me that this is a case where information would be crucial.

People wouldn't go off out of ear shot if they realized.

The question of the fallibility of the device, I think, is what needs to be told to people. Then they can judge for themselves if, even with those fallibilities, they still want to use the machine.

Mr. NIELSON. You are saying it is better than nothing, but not much?

Ms. CHELIMSKY. Right.

Mr. NIELSON. I understand most recalls include class 2 devices which are not required to be reported. Does this cause a particular problem?

Ms. CHELIMSKY. The fact that there weren't any performance standards developed means that the final outcome is that they go through almost without any regulation. I think one of the interesting parts of the analysis that we did——

Mr. NIELSON. My question is, are most of the recalls from class 2 because they don't have those standards?

Ms. CHELIMSKY. No, I don't think so. I think what that shows is very simply you can't predict which kinds of devices are going to have problems.

The fact there are so many recalls that were low risk I think is very interesting.

No, I don't think it is because they have no standards. I have no ability to make that link from the study that we did.

Mr. NIELSON. When manufacturers undertake recalls without notifying FDA, does this present problems?

Ms. CHELIMSKY. I think it does for the reasons that Mr. Bowsher said earlier, which is that very simply, it leaves the whole discretion in the matter at the manufacturer's level.

I also think it is a problem in the sense we were hoping for the problem reporting system to provide early warning to FDA. If the manufacturers are not telling FDA about recalls—which indicate problems—and perhaps they have not told them about the problems either, that means that what you are introducing here is a major gap in what FDA needs to know.

Mr. NIELSON. Should FDA require them to announce every time they have a recall?

Ms. CHELIMSKY. Yes. We think——

Mr. NIELSON. That is not my question.

Should the FDA require them to tell them?

Ms. CHELIMSKY. I think they should.

Mr. NIELSON. Sometimes a company reports to FDA only when a death or serious injury occurs. If it has nothing to do with the machine itself or if it is a misuse of the machine, they don't report it. They also don't report it when there is success.

Are we getting statistics which are only including the worst-case possibilities?

Ms. CHELIMSKY. You are bringing up a very, very good point. This is the problem of the universe. We are not getting the universe at all. We don't know which are the good devices, and we don't know which are the bad ones.

We don't know what the total system is. That is why we are asking for better use of statistics in this system.

Mr. NIELSON. Are there cases when the manufacturer doesn't report when he thinks the machine has been misused?

Ms. CHELIMSKY. Yes.

Mr. NIELSON. What happens in that case?

Ms. CHELIMSKY. The FDA goes in and does an inspection normally, finds out what has happened, looks at the number of problems that have been reported and normally sends a notification of adverse findings if, in fact, they determine they should have been reporting.

Mr. NIELSON. Is this a matter of product liability?

Should we have a product liability insurance to protect the manufacturer as well as to protect the patient?

Ms. CHELIMSKY. The system is certainly there, but I don't think that in any sense obliterates FDA's role.

Mr. NIELSON. I wonder if we had a little insurance liability to protect everyone involved, it might make the manufacturer more responsible. It also might make for better protection.

Ms. CHELIMSKY. We have not studied that issue.

Mr. NIELSON. I know the chairman disagrees with me on that point.

But there needs to be some way to protect the practitioner as well as the manufacturer without needlessly risking the life of the individual.

I thank you.

Mr. ROWLAND [presiding]. Let me point out that one thing that a hospital reports a device being effective, that the hospital may be granted immunity in any litigation that would take place—just to follow up on a question that you raised there.

Mr. Bates.

Mr. BATES. Thank you, Mr. Chairman.

I think this is an important hearing and an excellent report. In trying to get a handle on this, an overview, if you would, I had a few questions that would go to maybe walking through the process and trying to determine the final impact on the patient or the consumer or user of these medial devices.

It seems to me, and I haven't completely read the reports, but only skimmed them.

But it seems that the effect on the patient is not directly reported on. Is that accurate?

Mr. BOWSHER. Yes, that is.

Our studies were here on the adequacy of reporting to the FDA and to what happened after the reports had been sent to the FDA. We were not looking at the patient impact.

Mr. BATES. We weren't looking at that in this report. Could you—I guess the fact that the reporting appears to be so inadequate that we really don't know the extent of the problem.

But my first concern would be, let's say you were a patient with one of these medical devices and you went in for treatment and you got worse instead of better. I mean is that implausible under these circumstances?

Ms. CHELIMSKY. It depends on the device, whether there would be any relation. It seems to me that it is very plausible.

It could very well happen, depending on what the device was, thinking of any of the implants, any of the things that we have seen that are related to devices.

Mr. BATES. Right.

It would seem—is there any intent to follow up with a report that would focus on that? It seems to me that what it would have is how many people have died, how many people have gotten worse as a result of these devices that are on the market.

I think the point that has come up over and over is product liability. We have debated that issue thoroughly in this committee.

But it seems to me if you were to file a suit under product liability law to claim damages for an improper device or inadequate or ineffective medical device, that you would first have to know that it was inadequate.

I don't know where we get at that. That was not your charge.

Mr. BOWSHER. There were other reports going back to the Cooper Report that did point out some of the impacts of these problems. That is why some of the added reporting was enacted by the Congress.

So it was done in light of the fact that you were actually incurring problems out there and thought with better reporting you might be able to deal with these better. Our work here focuses pretty much on how well is that reporting done.

Mr. BATES. Thank you.

Mr. WAXMAN. Thank you, Mr. Bates.

Mr. Bowsher and Mrs. Chelimsky, I think you have done an excellent job on this report that you have submitted to us today along with the others you have done over the last several years with regard to FDA monitoring of these medical devices.

I agree with you. We have a very distressing, disturbing situation where FDA is not doing the kind of job we had hoped when we adopted the 1976 law and that we would expect on behalf of the public in terms of protecting them from unsafe medical devices.

We will continue not only to monitor the situation, but I think we have got to change the law to give a clear statement of what is expected.

I appreciate your being with us.

Thank you very much.

Next, Mr. and Mrs. Michael Davis from Corpus Christi, TX. They are accompanied by their attorney, Mr. Cage Wavell.

We want to welcome you to our subcommittee hearing this morning We appreciate your being with us. I know it is not easy to talk about the loss of a loved one. For this, we are particularly grateful for your being willing to come to Washington and appear before us today. We hope your comments and what we learn in your very tragic experience may be helpful as we try to prevent these kinds of things from happening in the future.

STATEMENT OF MICHAEL B. AND CORY J. DAVIS, CORPUS CHRISTI, TX, ACCOMPANIED BY CAGE WAVELL, COUNSEL

Mr. Chairman and members of the subcommittee, we appear before you today to advise you of the birth of our first born son, Michael Boyce Davis, Jr., and the unnecessary and tragic circumstances surrounding his death on March 17, 1987.

Michael was 6 weeks premature when he was born on December 23, 1986. We were not able to take him home from the hospital until the doctors said he was strong enough to be safe at home.

Finally we did get to take him home about January 27, 1987. We were able to take him home but the doctor said we had to keep him on the monitor to be safe so that if he quit breathing the monitor would sound and we would know and be able to give him CPR if it was necessary. The monitor was an Aequitron Model 8200 monitor.

Before we took Michael home we were given training in CRP and how to use the monitor. We were told that if any problems ever developed with the monitor or with Michael, that the monitor would alarm. We were never told that there could be a time when Michael could quit breathing and the monitor would not sound the alarm.

Then on March 17, 1987, when Michael was almost 3 months old, Cory woke him up at 4 o'clock in the morning to feed him. She fed him and everything was okay, and she went back to bed. Michael was sleeping with us in our bed and he was hooked up to the monitor.

Then we woke up at 7 a.m., but when I turned Michael over, he was white and we knew something was wrong. The monitor was not sounding the alarm and showed that everything was normal but Michael still was white and did not move. We tried everything we could to save him but nobody could do anything.

Losing our first baby was very hard to deal with. We knew that if the monitor had gone off and sounded the alarm then Michael would still be with us today, because he was a healthy baby and had not had any other problems since we got him out of the hospital. We finally decided that there might be other babies that would die and other parents would have to go through what we went through if we didn't do something about the company that made the monitor that didn't work. So we talked to a lawyer, and the lawyer sued the company for us that made the monitor and found out that the company knew for years before that the monitors had alarm problems and that many babies had probably died because

the alarm had failed to go off like it was supposed to—the same thing that had happened with our baby.

Mr. WAXMAN. Thank you very much for telling us about the situation. What were you told when you were given this monitor to use? Were you told that there might be problems? Were you told you could have confidence in that monitor for the baby?

Mr. DAVIS. We were never told there might be problems that might occur with the monitor. The only thing we were told, we could not take our baby home without use of the monitor. There was no assurance that the monitor might malfunction or have any problems with it. We were never notified of anything like that.

Mr. WAXMAN. What was the monitor supposed to do?

Mr. DAVIS. In the event Michael quit breathing—they had set it for 15 or 30 seconds. If Michael quite breathing or his heart would stop beating, then the monitor would have an alarm to sound off. That would give us the chance to perform CPR on our son.

Mr. WAXMAN. The monitor just didn't go off at all?

Mr. DAVIS. No, it did not.

Mr. WAXMAN. You of course have gone through a situation that other families all over the country are concerned about as they face using this kind of device. I know parents are going to be calling and asking what they should be doing. Do you have any advice for them?

Mr. DAVIS. The same thing that I have said over and over. Just to check it out, to see what you have and to do everything possible to do what you can about it. You know, nothing is going to be 100 percent guaranteed, but if the people do have an idea of what they are facing, then they may have a chance.

Mr. WAXMAN. You just wish you would have been at least told that there might have been a problem?

Mr. DAVIS. Yes. I believe that if we were told, it would have never made anything easier, but we would have been more aware of the problem. We would have been more—we wouldn't have had so much confidence in the machine and been able to, you know, go about and still be able to perform what we needed to do with the warnings of what might happen.

Mr. WAXMAN. You have your attorney with you. I gather this is all in litigation at the present time. Is that correct?

Mr. WAVELL. That is correct.

Mr. WAXMAN. Mr. Wavell, I understand that the first time anyone outside of Aequitron learned about the existence of these 50 death complaints was when you received a document called the H-1 death list during—HI list during the course of pursuing the Davis case. Is it correct the company reported virtually none of these deaths on their own? How did the company explain this?

Mr. WAVELL. That is correct. That is called the HI death file. It was later told to us after we had received it. The opposing counsel expressed some surprise that we had it and then later informed us that—as did the corporate representative—that that death file had been prepared pursuant to the litigation from complaints that Aequitron, the device manufacturer in this case, already had.

Mr. WAXMAN. The manufacturer had a complaint file that indicated that there had been how many deaths at that point?

Mr. WAVELL. On the death file there were over 76 entries, not all of them clearly denoted death. There were clearly over 50 deaths. MDR's had been filed on only one of those occurrences.

Mr. WAXMAN. So the manufacturer—the MDR is a medical device report to FDA, is that correct?

Mr. WAVELL. That is correct. The MDR is a report required by 21(c), section 24, done by the medical manufacturer to the FDA in any instances in which death or serious injury has occurred or could occur. In the case of Aequitron, there were numerous MDR's, which have been filed in cases where malfunctions had occurred, but no death and no serious injury.

However, in every case where there was actually a death, Aequitron did not file the MDR's.

Mr. WAXMAN. Did you contact FDA?

Mr. WAVELL. Yes, we did.

Mr. WAXMAN. Did you ask them to do anything? What did they say? Did they seem to know that there had been problems with this monitor before you contacted them about the Davis case?

Mr. WAVELL. That is correct. We verified that by going through the Freedom of Information Act to obtain various correspondence between the FDA and the manufacturers, in this case Aequitron. We found that there were numerous problems that were known with the monitor. We then——

Mr. WAXMAN. Known by FDA?

Mr. WAVELL. Yes, pursuant to their inspections of the administration monitors. We then proceeded, once we obtained the death file, to inquire of the FDA as to why the Davis case was not included in the death file and also to inquire if Aequitron had in fact filed the require medical device reports pursuant to 21 CFR 803. We found Aequitron had not filed those MDR reports and essentially no action had been taken by Aequitron with respect to that.

Additionally, Aequitron failed to file any report concerning the Davis incident. In fact, the Davis incident, which resulted in death, was not even included in Aequitron's own death file, which led us to believe that the death file was made up of occurrences far more clearcut than the Davis occurrences. The Davis occurrence, of course, is a clearcut case of death with respect the monitor was a contributing factor.

Mr. WAXMAN. What we have is, in this particular case, a baby died because a device didn't function correctly. It didn't give the alarm it was supposed to give, and the manufacturer didn't even have that on a list of problems and deaths that it kept on file, and FDA was never told about this case? Is that correct?

Mr. WAVELL. The Davis occurrence was known to Aequitron and there were a couple of telephone messages denoting that fact. However, Aequitron never included the Davis case on the death file, nor did they ever, in fact to this day, they have never filled out any type of MDR with respect to the Davis case.

Mr. WAXMAN. You are pursuing litigation in terms of whether there is civil liability. Our concern is not about that. Our concern is whether FDA knew about what was going on with this device, that there had been problems, whether the manufacturer was letting FDA know about the problems, and why no action had been taken for the longest period of time.

Mr. WAVELL. Well, with respect to that, back in September 1988, over 1 year and 2 or 3 months ago, our office informed the FDA of the fact that the death file had been produced and that the Davis case was not on it.

The FDA took essentially, from our perspective, no action with respect to the receipt of the death file. The only semblance of any action taken by the FDA was the October 18, 1988 letter by Ann B. Holt, to Aequitron complaining of Aequitron's failure to adhere to reporting requirements set forth in section 802 21 CFR. That correspondence by Ann Holt made it abundantly clear to Aequitron that their reporting was not in compliance with the FDA standards. Notwithstanding, Aequitron still did not file MDR's on the other 50 deaths contained in their own death file.

We then contacted, after it appeared that the FDA contact was not going to render any action, we contacted the Inspector General. The Inspector General was rather tied up on other cases at that time. We then proceeded to contact the General Accounting Office. We finally got in touch with Dr. Dillingham, and that is when things began to happen.

Mr. WAXMAN. Thank you very much for your presentation to us.

I want to make note of the fact that we have asked the Inspector General and GAO to give us a report on this particular case. So there is a continuing surveillance of the issue. We look forward to hearing more from them about this Aequitron apnea monitor. But it does illustrate the issue that is before us in a broader sense, that FDA is not getting the information about devices, that it never reviewed them before they went on the market as to safety. Then when FDA has heard a little bit about the problem, it didn't seem to be acting upon it to make sure that the public was being protected.

Let me call on my colleagues.

Dr. Rowland, do you have any questions?

Mr. ROWLAND. Thank you, Mr. Chairman.

I suppose one of the most traumatic experiences for new parents is to lose a child through sudden infant death syndrome. We are concerned here, particularly with the medical devices and the post-surveillance system. But I do want to ask you some questions about what happened in your situation. I believe that you indicated that at the time you left the hospital you were advised you should have an apnea monitor for your baby when you went home?

Mr. DAVIS. Yes, sir, we were.

Mr. ROWLAND. What was the reason given to you for that?

Mr. DAVIS. Our son was 6 weeks premature and he was not up to his weight when he was born, which was in compliance, or which meant that his lungs were not fully developed. The apnea monitor was for the use of, since he wasn't fully developed, right, if he did have any problems with his lungs, or you know, something would happen, that the monitor was there for a safety reason, because he was not, he was not as functional as, say, a full size, full term baby was.

Mr. ROWLAND. At the time you left the hospital, who talked with you about—not the name of the person, but in what capacity did someone talk to you about the monitor and who advised you about the monitor?

Mr. DAVIS. We were in Oklahoma Memorial Hospital. They have a gentlemen there by the name of Gary Pearson that instructed us on the use of the monitor. He basically said that the back of the back of the monitor which has everything to be adjusted on it, had been adjusted to Michael's sensitivity for the apnea problem. They basically just taught us the use of CPR in case anything did happen, and how to connect the monitor to our son.

Mr. ROWLAND. He didn't advise you about all of the capabilities of the monitor, didn't give you a sheet, like an informed consent type of sheet, or information that would advise you about the deficiencies the monitor might have and anything of that nature? You got no such advice like that?

Mr. DAVIS. I really don't remember at this time. He may have done it. I knew we did get a manual with the monitor. To my recollection—I don't remember at this time.

Mr. ROWLAND. The manual that you got didn't advise you—the reason I am asking you these questions is a whole chain of events, and am trying to get things together to try to improve this system. The manual that you received didn't advise you about the defects that the monitor may have, how it was not capable of doing everything that you might want it to be doing?

Mr. DAVIS. I don't believe it did.

Mr. ROWLAND. Let me ask your attorney there a question.

In pursuing this, have you learned whether or not there are any other suits pending with reference to this particular monitor, type monitor?

Mr. WAVELL. Yes, there are other suits pending pursuant to the Aequitron Model 8200, which there are probably 25,000 to 30,000 manufactured. One such case is the Nolan case. Their attorney is Eric Weinberg, seated on the front row of this hearing. He is knowledgeable of the facts and circumstances surrounding the manufacture and the defect of this monitor.

Mr. ROWLAND. There are several cases prior to yours. This is just one?

Mr. WAVELL. Ours was, as far as we know, the first such suit concerning the 8200 monitors. There are approximately six other suites, we believe, pending at this time. I think that there may be others. We gained this information partially through discovery in the lawsuit and also through the report of the company itself, their published report.

Mr. ROWLAND. How many deaths were reported by the company after you began to get into this?

Mr. WAVELL. After we got into the matter, as I understand it, there were either four or six additional reports made by MDR. I believe there were 10 instances which were discussed with the FDA. Even though the death file had over 76 injuries, there were 18 of those which were discussed with the FDA. That resulted in either four or six additional MDR's being reported.

I think it is important for you to understand, sir, that when these additional reports were required, that was done pursuant to a conversation between Aequitron personnel and the FDA. It was not exactly—we don't believe there was full disclosure of all the facts. Had there been, we think that there would have been at least been

10 MDR's and probably 76 MDR's that would have been required to have been involved.

Mr. ROWLAND. Thank you, Mr. Chairman.

Mr. WAXMAN. Mr. Nielson.

Mr. NIELSON. I appreciate your statement. I know it is very hard for you to do this. You did very well.

Let me ask you two questions. I want to pursue the line asked by Dr. Rowland again.

When the doctor said you could take the baby home provided you had the monitor, did the hospital play any role? Did the hospital recommend you go home or stay? Did they enter into the picture at all?

Mr. DAVIS. The doctor was the one that spoke with us about the monitor. The only one that I can really remember saying anything was the doctor himself, advising us that we had to have the apnea monitor to take our son home.

Mr. NIELSON. If the doctor had—I don't know what the doctor might say at this point if you chose to go after the doctor as well. Would he have any reason to suggest that you put pressure on home to take the baby home against his advice?

Mr. DAVIS. I don't think so. I mean, when a parent has a child, the parents have a child and he has to stay in the hospital for say a month and a half or so, there is always, you know, you would like to have your child home with you. But at the point where, to put pressure on anybody and to make them to where they would release our son before he was ready, I don't believe we did.

Mr. NIELSON. You didn't pressure the doctor at all by saying, we have got to have him home, or anything of that nature?

Mr. DAVIS. I don't believe we did.

Mr. NIELSON. He didn't show a great deal of resistance to your suggestion that he go home?

Mr. DAVIS. They were really concerned about him being able to go home, you know, having the proper weight and being able to breath on his own and everything. They showed a lot of concern about that.

Mr. NIELSON. When the doctors suggested that you have him monitored, did he talk about the fact that perhaps sometimes the monitor didn't work, as was mentioned by the GAO? In sleeping apnea they can't always tell when he is breathing. The monitor may not pick up when the breathing stops because of other sounds in the room. For example, if the baby was in your room, as he was, the monitor might have been picking up your breathing sounds instead of the baby's? Is that possible?

Mr. DAVIS. I don't believe so.

Mr. NIELSON. The doctor didn't alert you to any of those problems?

Mr. DAVIS. I don't remember, but I don't believe so.

Mr. NIELSON. Are you aware of other instances such as yours?

Mr. DAVIS. Here recently I had a discussion about the Nolan case. I really don't know that much about it except that they do have a suit pending also.

Mr. NIELSON. I have a number of other questions, but I think most of them have been asked. It is very difficult.

Let me ask the mother in the case. When the baby awakened you at 3 o'clock to feed, the baby was perfectly normal?

Mrs. DAVIS. Yes, it was perfectly normal.

Mr. NIELSON. The baby nursed normally and everything at that time, at 3 o'clock?

Mr. DAVIS. Sir, you will have to speak up.

Mr. NIELSON. When you fed the baby in the middle of the night, did the baby nurse normally?

Mrs. DAVIS. Whenever I fed the baby at possibly 4 o'clock, everything was normal.

Mr. NIELSON. You had no reason to——

Mrs. DAVIS. No, none whatsoever.

Mr. NIELSON. The baby was not lethargic at all? The baby was nursing like normal?

Mrs. DAVIS. Yes; yes, sir. He was. Everything was okay. I had no reason to suspect anything.

Mr. NIELSON. I surely sympathize with you. I know we have just dedicated a little grove in my home State, my home district with, for, a tree for each victim. There were 70 that died in my district last year. I sympathize with you.

The problem is very difficult. I had a little brother that did not live, if not for a different reason. I remember how tragic that was, traumatic that was for the rest of the family. I was only five at the time. But even at that time I was very sad.

I appreciate what you're going through. I appreciate your coming here and telling us about it. If it may be of any comfort to you, what you tell us here and the actions you take here may have some help in saving others in your same circumstances.

I thank you for coming.

Mr. WAXMAN. Thank you, Mr. Nielson.

Mr. Bates, do you have any questions?

Mr. BATES. Thank you, Mr. Chairman. These are certainly tragic circumstances we have to respond to. My sympathy is for you under these circumstances.

The question that I have dealing with this particular incident really, I think, would be directed toward your attorney, Mr. Wavell. Has the FDA or some response entity checked out the equipment and determined that it did, in fact, malfunction or not function properly?

Mr. WAVELL. Yes. There was a Dr. Joseph Dyro, who is a biomedical engineer and specialist in Stonybrook, NY. He has had many years in the field, has written several papers for the Government in addition to his other duties. He checked this monitor out. The Nolan monitor was also checked out by Mr. Dyro.

The Nolan monitor was checked out by an outfit known as ECRI. Dr. Dyro's testing the false respiration trigger was existent on both monitors, most recently on the Nolan monitor.

The machine was hooked up to a doll, which, of course, should have no vital signs, but the machine indicated that everything was alive and well, heart beating well, respiration in order on an inanimate object.

Mr. BATES. Did the FDA in their initial testing determine there was a similar problem, or is this—I guess what I am trying to get

at is, is this a problem with all of the monitors, or was this particular piece of equipment improperly constructed?

Mr. WAVELL. No, sir. It is a problem with all of the 8200 monitors. The FDA has known about it. The FDA has corresponded with Aequitron about it.

We also understand from a Dr. Yaught, Y-a-u-g-h-t—I believe I've got the name right; I might be in error on that—that the Health Dyne monitor back in 1983 had such a problem of false respiration trigger; that is, indicating breathing where it did not exist. The FDA caused Health Dyne to put a filter on the monitor.

In the case of Aequitron, however, for some reason unknown, Aequitron was not required to place a filter on their monitor even though the Aequitron monitor did also exhibit the false respiration trigger known both to Aequitron and the FDA.

There is additionally an electrostatic discharge phenomena which causes problems with the machine. That also was addressed by the FDA in correspondence to Aequitron.

One other thing that may be of interest to you is that the Aequitron monitor can be rendered totally ineffective or inoperative by wrong adjustment of the sensitivity knob which is to be set by the physician or the distributor.

It is interesting to note that the FDA, had they reviewed the Aequitron manual which is provided to the physicians, which have noted there is no instruction in that manual to tell the physician how to set the sensitivity knob.

So on its face, a mere examination of the literature could have prevented many of the occurrences where the monitor is rendered inoperative; that is, it fails to sound when the child quits breathing.

Mr. BATES. We have heard a lot about product liability and what it would do or wouldn't do. There is a suit filed, I presume, in this case?

Mr. WAVELL. There are six suits that I am aware of.

Mr. BATES. You filed one?

Mr. WAVELL. I filed one on behalf of the Davises. Mr. Eric Weinberg, seated on the front row, filed one on behalf of the Nolans.

Mr. BATES. I am also presuming the FDA is exempt from liability for—that is not the issue. It is an issue that concerns me.

Mr. WAXMAN. Would the gentleman yield to me?

We have asked the GAO and the Inspector General to review the performance of FDA in this case and the whole situation, so we will be getting a report. That report was not completed as of this hearing date.

Mr. BATES. Well, I guess my concern is that the FDA has a responsibility here, but I think it would be exempt from being a party to the lawsuit which it would seem to me then might account for some of these lapses in reporting.

I was just wondering, are they cooperating in the suit?

Mr. WAVELL. We have not had a great deal of contact with the FDA, other than enough to establish that we were suspicious of the FDA's relationship with Aequitron to the extent that we question their desire to regulate Aequitron.

We then pursued it to the Inspector General and the General Accounting Office. My clients, the Davises, do not wish to take any,

with respect to bringing any lawsuits against the U.S. Government or subdivisions such as the FDA or anyone else.

They simply are upset at the manufacturer who they believe caused in a continuing sequence the death of their child by not giving adequate warnings with respect to the monitor that they entrusted the life of their child to.

Mr. BATES. Thank you.

Mr. WAXMAN. Just to clarify something for everybody, this particular device was approved by the FDA as being equivalent to another device like it. It did not get a preapproval by FDA where they looked to see whether it was safe and effective.

They assumed if it was equivalent to another device on the market that that was enough. They therefore let it be used. It is the kind of device, three categories—it is category 2. It was not viewed as particularly dangerous.

FDA, under the law, was supposed to set up a performance standard. As I understand, no standard was set for this device. In fact, FDA never set a performance standard for any class 2 device.

They are in the process of working on standards for this particular device, but it will be many, many years after the device has been on the market.

I just wanted to clarify that point.

Mr. ROWLAND. The gentleman raises a point about equivalency that is very disturbing, as you well know, in the generic drug problem we are now experiencing and the doubt that is cast on the bioequivalency of generic drugs.

Do we have a similar situation here that we are looking at a monitor that was supposed to be equivalent to some other monitor? Is that a process that we need to look at, Mr. Chairman?

Mr. WAXMAN. If the gentleman would yield to me?

Mr. ROWLAND. Yes, sir.

Mr. WAXMAN. This is clearly one of the reasons we are looking for the IGA's report. FDA has a lot of discretion as to what they consider bioequivalent.

Bioequivalent is not the same thing as substantially equivalent. Bioequivalent is what they look at for a generic drug.

Substantially equivalent means it is pretty much like a device already on the market. It is a similar kind of situation, although it is not exact. It is the kind of thing where we want to get some further thinking in terms of whether the law ought to be more precise.

Mr. Dannemeyer.

Mr. DANNEMEYER. Thank you, Mr. Chairman.

Mr. and Mrs. Davis, our hearts go out to you for what you have experienced. We thank you for bringing this information to our attention.

I know it is difficult to even talk about it, and I understand that. I have some questions. Your counsel may be better to answer them. You can kind of join in with him. It is okay.

Counsel, when the device was given to the Davises to take home, was it in a container or package of any kind?

Maybe you could tell me this: Has the deposition of your client been taken?

Mr. WAVELL. Yes, it has.

Mr. DANNEMEYER. When was it taken?

Mr. WAVELL. It was several months ago, about 4 or 5 months ago.

Mr. DANNEMEYER. Both Mr. and Mrs. Davis?

Mr. WAVELL. Yes. I can let Mr. Davis answer that question.

Mr. DAVIS. Yes, sir, it was in a box. It had a styrofoam protectant around it. It was placed into a box.

When we took our son home, because at the time we were taking him home, we were able to keep an eye on him and not be—you know, we were able to hook the monitor up; but at the time, we were able to watch him in case anything happened to him. But the monitor was taken home in a box with styrofoam protecting it.

Mr. DANNEMEYER. Were there instructions in that box when you unwrapped it as to how to use it?

Mr. DAVIS. There was a manual with it, but the manual is not the proper manual for the 8200 model when we were given a manual for it. Everything else was just that we were told that everything had been set.

We were properly instructed on the use of the monitor, how to connect the chips and everything—that is what I call them—the pads that go on the side and everything. We were told that everything had been set to the sensitivity of our child and that the only thing we needed to do was to hook the monitor to him.

Mr. DANNEMEYER. Were these instructions, so far as you know, clear to you? Did you sit down and read them over?

Mr. DAVIS. Yes, we did.

Mr. DANNEMEYER. How long after you began using the device did your child pass away?

Mr. DAVIS. Approximately a month and a half. I am not sure. I'd have to look at the dates.

Mr. DANNEMEYER. During that month and a half, did it ever sound off that something was amiss?

Mr. DAVIS. Yes, sir. We had one instance where we hooked our son to it, and it alarmed and kept on alarming. We did everything we could to change, say, they gave us two sets of chips and two electrodes and also two belts which connect the chips to the baby. We changed everything. We kept cleaning the chips off and using the jelly that they had suggested we use.

We had problems with it at that time. We stopped using the monitor. We contacted some physicians to find out what we could do about it. At that time, my wife and I took turns watching our son 24 hours a day. We never got any response within a day or so.

We decided to try the monitor again, and we just hooked it up and plugged—you know, hooked it up and turned it on, and everything was working fine. We went ahead and used it until we got further instructions on it.

Mr. DANNEMEYER. After you began—when you installed the monitor, was there any means whereby you could test it to see if it was working all right?

Mr. DAVIS. Excuse me?

Mr. DANNEMEYER. Was there any means whereby you could test the device to see if it was working okay?

Mr. DAVIS. None other than to hook it up to our child. We knew that he was breathing and had a heart rate. And just hook it up to

him. If it worked, it worked. There was really no way to test the monitor.

Mr. DANNEMEYER. Thank you very much.

Mr. DAVIS. Thank you.

Mr. WAXMAN. Mr. Sikorski.

Mr. SIKORSKI. Thank you, Mr. Chairman. I want to thank both panels and all the witnesses for their assistance and ask unanimous consent to have a statement placed in the record.

Mr. WAXMAN. Without objection, that will be the order.

Mr. SIKORSKI. Thank you.

[The prepared statement of Hon. Gerry Sikorski follows:]

STATEMENT OF HON. GERRY SIKORSKI

Over a decade ago Congress passed the Medical Device Amendments of 1976 to assure that the most intimate and vital health care items by Americans would be safe and effective, and it charged the Food and Drug Administration with fulfilling that statutory mandate. Today, the Government Accounting Office will present testimony that reveals the appalling extent to which the FDA and too many in the medical device industry have failed to live up to that promise. Industry has not met reporting requirements and the FDA has been negligent in its oversight. Consequently, the very credibility of the device approval process is subject to question. The latest GAO findings confirm and expand upon GAO's reports of May 1987 and February of 1989. Only this time, this subcommittee will not rely on FDA assurances that the system has but a few kinks that can be worked out. It will not accept one more excuse from FDA for its failure to responsibly regulate, arguing "the product recall system works well within the resources and legal authority given us by Congress." These are the sounds of senior political appointees covering their backsides. They have resisted our pushing, pulling, pinching, cajoling, and campaigning for more expertise and resources at FDA. For FDA now to argue limited resources is both patently wrong and pitiful. On issue after issue, year after year, FDA political policy makers have chosen to swallow the OMB line of "we can do more with less." They are right in the sense they have made more Americans ill and more Americans dead with less resources and less enforcement of America's Food and Drug laws. On pesticides, on food poisoning, on generic drugs, on counterfeits, and quackery, the FDA hasn't kept up with the threats, yet.

I want to commend the Chairman for his vigilance on this issue and his work on the Medical Device Amendments of 1989. I stand ready to assist him in his efforts to enact a tough bill that will build up public confidence in the safety of America's medical device industry.

It has to be understood by all that the benefits to public health attributable to the contributions of thousands of medical devices are both incredible and just beginning. They save thousands and thousands of lives and make hundreds of thousands of lives more livable, more comfortable. My home State of Minnesota is on the technological cutting edge of the medical device industry and we are proud of our contributions to the improvement of human health. But that is not the issue before this committee today. GAO tells us that many manufacturers are not complying with current law's regulations requiring them to report serious problems with their devices. In fact, we are told that even when defects or malfunctions could cause serious injury or death some manufacturers have withheld information from FDA. Some companies seem to be playing semantic games when human life and limb is at stake—and that's unacceptable. Companies should err on the side of reporting; not on the side of omission. And FDA should enforce the law. Reporting is the public's, the health professionals', the manufacturer's and the FDA's first line of defense against deadly malfunctions, defects or failures—right now it's not even an effective fall back position.

We will also hear testimony from two families. One of those families, the Davis family lost their infant son Michael because of the alleged failure of a heart and respiratory monitor manufactured by a Minnesota company, Aequitron, Inc. We are profoundly troubled by the information regarding this case and extend our deepest sympathies to the Davis'. We understand the IG of the Department of Health and Human Services is conducting an investigation into this matter and we anxiously anticipate their findings.

In a larger sense it must be understood that any company that takes advantage of regulatory loopholes, semantics or interpretational semantics is gambling with the

public health and will undoubtedly injure itself and its reputation—and it appropriately will suffer the consequences. It is becoming increasingly evident that we can not rely on too many manufacturers that have economic and legal interest in keeping devices on the market to abide by the current reporting "honor system." Look at the numbers during the 4 year period studied by GAO: 31 products recalled in the high-risk category—48 percent not reported to FDA; 792 products recalled in the lowest risk category—92 percent not reported to FDA; and 422 products recalled in the lowest risk category—92 percent not reported to FDA.

Lives have already been lost and lives remain at stake as we address the present systems' defects. There is no time for delay. I hope that this will be a bipartisan effort to arrest these problems and rejuvenate the American people's confidence in medical devices and the regulatory agency responsible for monitoring them.

Mr. WAXMAN. Thank you.

We want to thank you very much for being here to tell us about your experience. Our hearts do go out to you, our condolences. We hope from this session today as we look at these medical device problems, maybe we can prevent this sort of thing from happening to a future child. Thank you very much for being with us.

That concludes the hearing for today. The subcommittee now stands adjourned.

[Whereupon, at 11:30 a.m, the subcommittee was adjourned, to reconvene at the call of the Chair.]

MEDICAL DEVICE SAFETY

TUESDAY, JULY 17, 1990

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 9 a.m. in room 2322, Rayburn House Office Building, Hon. Henry A. Waxman (chairman) presiding.

Mr. WAXMAN. The meeting of the subcommittee will come to order.

This morning, the subcommittee will receive testimony on H.R. 3095, the Safe Medical Devices Act. Our hearing will be divided into two segments due to a meeting of the full committee. The hearing will adjourn at 10 and reconvene at 1:30 p.m. The first witness at the afternoon session will be Acting FDA Commissioner James Benson.

Today, we continue a series of hearings the subcommittee has held about problems in assuring the safety and effectiveness of medical devices. The safety and effectiveness of medical devices has an all-too-human face. At our last hearing in November, we heard from a couple who lost their young son due to the apparent failure of an apnea monitor. At issue was the manufacturer's failure to adequately inform FDA of potential problems with the device.

We also heard from the Comptroller General of the United States. In the past 4 years, the General Accounting Office has issued eight reports for the subcommittee on the medical device regulatory process. The Comptroller General testified that there are "several shortcomings in both the premarket review and postmarket surveillance systems for medical devices."

He concluded that serious questions are raised about the ability of these systems to protect the American people "from unsafe and ineffective medical devices."

The work the subcommittee has received from the GAO paints an unnerving picture. It shows manufacturers who profit from the sale of medical devices acting without FDA oversight in deciding whether to keep their devices on the market when problems surface. Even when recalls involve the strong likelihood of serious injury or death, the FDA knows about the problem in advance only half the time.

The inescapable conclusion is that the 1976 medical device law is not serving the public interest. The overwhelming majority of medical devices now being allowed on the market have not been shown

to be safe and effective. They are being allowed on the market through a dangerous regulatory loophole.

In addition, of the small number of devices FDA has granted premarket approval to since 1976, nearly one in seven has been recalled. Half of these recalls involved problems in device design. This raises grave concerns about the adequacy of the FDA approval process.

Clearly, reform of the medical device law is long overdue. H.R. 3095 was introduced by the distinguished chairman of the full committee, Mr. Dingell, and myself. It incorporates needed reforms in three stages of medical device regulation:

One, it phases out the section 510(k) loophole to require that the most dangerous medical devices be approved for safety and effectiveness.

Two, postmarketing surveillance: For the first time, hospitals and other major medical device user facilities would be required to report deaths and other serious problems with medical devices to the FDA. Manufacturers would be required to report all recalls and repairs done to eliminate health risks to the FDA.

Three, recall. Once FDA determines that a medical device poses an unreasonable risk of substantial harm to the public health, the device could be removed from the market. In addition, the most dangerous devices are required to have identification codes to help notify patients when health risks are involved.

This morning, the subcommittee will hear the results of a new study the Department of Health and Human Services Inspector General Richard Kusserow has conducted on medical device regulation. Their review includes a detailed study of specific medical device recalls which illustrate additional problem areas that require the Congress' attention.

The findings of the IG and the earlier work by the GAO illustrate that every stage of the medical device regulatory process is open to questions. Serious deficiencies exist in getting products on the market, learning about serious health consequences from devices in use, and assuring the recall of problem devices.

The passage of H.R. 3095 is long overdue.

Before I recognize our first witnesses, I want to call on a member of the subcommittee, Congressman Jim Scheuer. Do you have an opening statement?

Mr. SCHEUER. I thank you, Mr. Chairman. I especially wish to commend you and Chairman Dingell and your fine staff for the ongoing efforts you have conducted to enact comprehensive medical device reform.

It was my privilege, Mr. Chairman, to work with you during the 94th Congress, when, along with faulty pacemakers and the Dalcon shield, Congress enacted the Medical Device Amendments of 1976; this similar act extended the FDA's premarket surveillance beyond drugs to medical devices.

I would like to discuss one issue very briefly, Mr. Chairman, before hearing from the witnesses, an issue that has been of concern to me for the last 7 years. I am referring to legislative efforts originating in the other body, which would require the automatic reclassification of one particular medical device, soft and rigid gas-permeable contact lenses; if the FDA failed to make a special deter-

mination within 1 year that those contact lenses should remain in class 3.

Mr. Chairman, in January 1981, the Contact Lens Manufacturers Association, CLMA, petitioned the FDA to place the contact lenses in question into a less restrictive classification.

Over a 3½ year period, public hearings were held, opportunities for submission of evidence were granted, and a scientific advisory panel was convened to review the substantial evidence submitted to the FDA.

After their extensive review, the FDA concluded class 3 was necessary to provide reasonable assurance of the safety and effectiveness of these lenses.

Having lost at the FDA, CLMA then petitioned the U.S. Court of Appeals for the District of Columbia Circuit, imploring them to overturn the FDA's decision. The court refused to do so. Having their classifications rejected first by the FDA on scientific grounds, and second, rejected by the court on legal grounds, the proponents of reclassification have spent the last few years on Capitol Hill trying to get the device reclassified on political grounds.

The automatic reclassification proposal considered in the past by the Senate, seeks to overturn one of the few decisions the FDA has reached, which comport with the goals we established in 1976, under your leadership, Mr. Chairman.

The threat of automatic reclassification, coupled with the unrealistic short timeframe of 1 year, creates a coercive environment, which is far more likely to yield a capitulation to perceive political pressures than a considered scientific judgment.

More important than this particular advise is the dreadful precedent that would be established by singling out any particular device for special treatment. We would start down a slippery slope in which any manufacturer who failed to make their case on scientific grounds, either with the FDA or with the courts, could seek to use Congress as a bludgeon to intimidate the FDA.

Now, I was delighted to read in CLMA's testimony that CLMA now supports H.R. 3095, especially the proposed changes dealing with transitional devices. While I regret that I may not be with you this afternoon for questions, I hope CLMA will clarify two things for me.

First, does this commitment to H.R. 3095 stand for the entire legislative process, both in this body and in the State? Specifically, does CLMA oppose Senate bill 1094, the automatic reclassification legislation pending in the Senate, which is quite clearly inconsistent with the approach of this subcommittee?

Me thinks you can't have it two ways. Which is it, gentlemen? Second, does this commitment to H.R. 3095 extend to the appropriations process? Two years ago, there was a tremendous effort in the Senate, assisted by CLMA and supported by CLMA, to circumvent this authorizing committee, this committee, by forcing the automatic reclassification of contract lenses by an AM to the FDA appropriations bill.

Now, we want to pass a comprehensive medical device reform bill, so your support of H.R. 3095 really, if it is to be meaningful, and if it is to be intellectually honest, must extend beyond the confines of this room if it is to have any meaning.

It must extend to the same legislation being considered on the Senate side. You can't support us here and oppose us over there.

I want to start—I want to conclude as I started, by commending Chairman Waxman and Chairman Dingell, the medical device bill which passed the House under their stewardship 2 years ago called for comprehensive reform without singling out for any special treatment any special device, and without threatening to rob the FDA of their authority to ensure the safety of a device after an arbitrary deadline.

The comprehensive bill you have drafted this year, Mr. Chairman, embodies the same sound principles. I stand ready to assist you in fighting to assure our final work product truly protects the public health and resists special interest pleadings.

I ask the record be kept open for additional information on the subject.

Mr. WAXMAN. Thank you very much. Without objection, the record will be kept open for further information. Further, the record will be kept open for opening statements by other members of the subcommittee.

[The prepared statements of Hon. John Dingell, Hon. James Scheuer, and Hon. Edolphus Towns follow:]

OPENING STATEMENT OF JOHN D. DINGELL

I thank the Health and Environment Subcommittee and Chairman Waxman for holding this hearing.

Mr. Chairman, as you know I have often expressed my very real concerns about the current regulation of medical devices and my absolute intent to address these issues. This is one of many hearings on the need for improved medical device regulation, and one of many statements I have made urging legislation to correct the flaws in the current approval system.

I do not intend to make life particularly difficult for the medical device industry. But it is clear that the current statute does not adequately protect the public from unnecessary risks. In addition, the FDA lacks the resources and the authority to enforce the law, so that the industry need pay only a passing acknowledgment to the requirements of the law, with little or no risk of penalties for infractions. The current system effectively rewards unscrupulous operators willing to bend or break the rules, and penalizes honest companies observing both the spirit and the letter of the law.

The FDA must have new and increased authorities to allow the proper premarketing scrutiny of devices and the appropriate postmarketing surveillance. The Agency also needs better enforcement authorities, and the means to ensure the best use of its personnel and resources. I intend to see that these are provided. I also intend to continue to work to boost the FDA'S overall statutory and material resources.

The chairman of the subcommittee and I have both declared our intention to move forward quickly with a legislative package. We anticipate a bill which will pass the House promptly, with corresponding Senate action.

What is at stake here is public confidence in the safety and efficacy of medical devices. As long as the industry has the public's confidence and trust, it will prosper and grow, and in both the short and long term, it too will benefit from this legislation.

I encourage those who share these concerns to bring them forward and we will be happy to work with you.

OPENING STATEMENT OF HON. JAMES H. SCHEUER

Mr. Chairman, I want to thank you, Committee Chairman Dingell, and your fine staff for your ongoing efforts to enact comprehensive medical device reform.

It was my privilege to work with you during the 94th Congress when alarmed by faulty pacemakers and the Dalkon Shield Congress enacted the Medical Device

Amendments of 1976. This seminal act extended the FDA's premarket surveillance beyond drugs to medical devices.

In the years since passage of the act, Chairman Dingell through the Oversight Subcommittee and Chairman Waxman through the Health Subcommittee, have been exceedingly vigilant in monitoring the effectiveness of the Medical Device Act. As their hearings earlier this year on the Shiley heart valve illustrate, the Medical Device Act is in need of reform.

Before hearing from our distinguished witnesses, I'd like to discuss briefly one issue in particular which has been of continuous concern to me over the past 7 years.

I am referring to legislative efforts, originating in the other body, which would require the automatic reclassification of one particular medical device—soft and rigid gas permeable contact lenses—if the FDA failed to make a special determination within 1 year that these contact lenses should remain in class 3.

In January 1981, the Contact Lens Manufacturers Association [CIMA] petitioned the FDA to place the contact lenses in question into a less restrictive classification. Over a 3½ year period, public hearings were held, opportunities for the submission of evidence and comments were granted, and a scientific advisory panel was convened to review the substantial evidence submitted to the FDA. After this extensive review, the FDA concluded that class 3 was necessary to provide reasonable assurance of the safety and effectiveness of these lenses.

Having lost at the FDA, CIMA petitioned the U.S. Court of Appeals for the D.C. Circuit imploring them to overturn the FDA's decision. The court refused to do so.

Having their reclassification effort rejected by the FDA on scientific grounds and rejected by the court on legal grounds, the proponents of reclassification have spent the last few years on Capitol Hill trying to get the device reclassified on political grounds.

There is a tremendous irony concerning the contact lens debate. Much criticism of the FDA focuses on their failure to execute the device reviews called for in the 1976 act. In this instance, by contrast, the act functioned precisely as it was intended. The act established a process for reviewing the classification of a group of devices. The FDA completed an extensive review in accordance with that process and reached a determination on scientific grounds. That determination was sustained in court.

The automatic reclassification proposals considered in the past by the Senate seek to overturn one of the few decisions the FDA has reached which comport with the goals and process we established in 1976. The threat of automatic reclassification coupled with the unrealistically short timeframe of 1 year creates a coercive environment which is far more likely to yield a capitulation to perceived political pressure than a considered scientific judgment.

More important than this particular device is the terrible precedent that would be established by singling out any particular device for special treatment. We would start down a slippery slope in which any manufacturer who failed to make their case on scientific grounds would seek to use Congress to intimidate the FDA.

I want to conclude as I started, by commending Chairman Waxman and Chairman Dingell. The medical device bill which passed the house under their stewardship 2 years ago called for comprehensive reform without singling out for unique special interest treatment any particular device and without threatening to deprive the FDA of their authority to assure the safety of a device after an arbitrary deadline. The comprehensive bill you have crafted this year embodies the same sound principles.

I stand ready to assist you in fighting to assure that our final work product truly protects the public health and resists special interest pleadings.

I ask that the record be kept open for additional information on this subject.

Statement of Hon. Edolphus Towns

Mr. Chairman, I commend you for holding this important hearing on medical device legislation. Unfortunately, I have another commitment this morning but I hope to return this afternoon for the second half of the hearing.

We all share the goal of ensuring that the safest possible medical devices are delivered to the public. Our constituents rely on these devices every day and, in many cases, not only do these devices improve the quality of life, they also are life-sustaining.

This is a research-intensive, competitive industry, one that is on the cutting edge of technology and makes a positive contribution to our balance of trade. As we craft

new legislation, we must be careful to preserve the incentives for innovation that have pushed the frontiers of health technology forward.

In this regard, I am particularly concerned about provisions of H.R. 3095 and previous legislation which would allow subsequent applicants to rely on data submitted to FDA by an innovator. This data that may be the product of research and clinical trials conducted over a lengthy period of time at great cost at the innovator. I, too, want to see our consumers benefit from lower prices. However, I believe that we should not take actions which may result in stifling innovation to the point that new medical products will not be brought on the market. Mr. Chairman, I hope that the subcommittee will give serious attention to this concern as we move forward with the legislation. I look forward to hearing from our witnesses this afternoon.

Mr. WAXMAN. It is a pleasure to welcome to our hearing this morning the Inspector General, Department of Health and Human Services, Richard Kusserow, who will report on the findings of the review of his office, recently completed, on medical device regulation.

We will also hear from Carl Wisler, Director of Planning and Reporting of the General Accounting Office's Program Evaluation and Methodology Division. Mr. Wisler will present the findings of a case study entitled, "Underreporting of Serious Problems with a Home Apnea Monitor." He is accompanied by Dr. Gerald Dillingham.

Gentlemen, we are pleased to have you with us. Your prepared statements will be in the record in their entirety. We would like you to proceed. And I gather, Mr. Kusserow, you are going to need more than the usual 5 minutes which we agreed to, but generally, we like to keep the oral presentation to around 5 minutes.

But we would like to hear from you first.

STATEMENTS OF RICHARD P. KUSSEROW, INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND CARL E. WISLER, DIRECTOR OF PLANNING AND REPORTING, PROGRAM EVALUATION AND METHODOLOGY DIVISION, GENERAL ACCOUNTING OFFICE

Mr. KUSSEROW. Thank you, Mr. Chairman. Of course, with me is Deputy Inspector General Michael Mangano, who just came back from last Thursday's meeting with you on another matter in a hearing. And indeed, I will try to highlight as quickly as I can, to get the major points across.

I certainly would not want to cut into the time of the next speaker, who—Dr. Sidney Wolfe, who is a recipient of the prestigious McArthur Award, so I do know you want to hear what he has to say as well.

As you pointed out, our office has been very heavily involved in conducting oversight audits, inspections and investigations throughout the FDA. For the past 10 years, I have been Inspector General. And most of our reviews have been at the request of the Commissioner of the FDA, and is consistent with the Agency's ongoing commitment to improve their efficiency, effectiveness and integrity.

In addition to that, you did mention the apnea monitor, which we were very much involved in at your request. In fact, much of what I am reporting on is also consistent with the request of this committee in terms of building up some sort of a record that will

allow you to really have legislation respond to the concerns that are being found, not only by our office, but of course, by GAO.

As part of our ongoing program of review, we have, in fact, been examining the medical device regulatory system. Our work has identified some weaknesses. Some of the more significant ones, I will go into a little bit with some detail, and also, I am prepared to answer questions on.

Also, you have indicated that we have a number of studies in this area. We do, and with your permission, we will make them available to the committee, including: "Internal Control Weaknesses in the Food and Drug Administration's Medical Device Section 510(k) Review Process," "Review of the Food and Drug Administration's Actions Relative to the Recall of the Medtronic Model 6972 Pacemaker Lead," "Review of the Allegations Made by Clark Research and Development, Inc., Against the Food and Drug Administration," "Review of Allegations of Defective Plasmapheresis Equipment Regulated by the Food and Drug Administration," and "Issues Related to the Food and Drug Administration's Regulation of Hemoperfusion Medical Devices." Also, I would mention, Mr. Chairman, that we have another report that will be out soon, and we will make that available. That is "FDA's Medical Device Regulation From Premarket Review to Recall." We will certainly bring that to the committee as soon as we have that available. [The reports referred to have been retained in subcommittee files.]

Our work in this area is really responding to an increasing public concern about the safety and effectiveness of medical devices. This is an ongoing effort, as was pointed out in the opening statements. That goes back to the late 1960's and early 1970's, when Congress passed the Medical Device Amendments of 1976 to the Food, Drug and Cosmetics Act, responding to these concerns.

The amendments provide a set of regulatory controls for marketing medical devices to curb abuses, and protect the American public. These amendments require manufacturers to notify FDA of their intent to market new medical devices. Section 510(k) of the act requires that 90 days prior to marketing a device, the manufacturer must inform FDA of its intent.

If FDA determines the device is substantially equivalent to class 1, class 2 or pre-1976 devices on the market, then one device can enter the market with only the section 510(k) notification.

If the device does not meet the test, then it must undergo a full PMA process.

Unlike the abbreviated section 510(k) process notification process, the PMA process involves an indepth scientific review to ensure the safety and effectiveness of the device. Currently, as you pointed out in your statement, most of the devices reach the market through the section 510(k) process, and from 1976 through 1988, approximately 94 percent of the more than 36,000 devices which went on the market, as well as device modifications, entered the market after the FDA determined the products were substantially equivalent to devices already on the market.

Our work, which we are reporting on today, is looking at the system, both from the frontend preceding approval, and then also the backend, after the product is on the market and if it is not in fact in the public interest.

Our review on the front end side of section 510(k) process found a number of material weaknesses which could impair FDA's mission of assuring a fair premarket notification process and negatively affect the public confidence in FDA's ability to protect public health.

I would like to go through, very, very quickly, the five major findings that we came up with that leads us to this conclusion. First, we found that FDA lacks written policies and procedures for sequencing the section 510(k) reviews and documenting the review decision.

What that means is that you can't tell whether applications are being taken in order, out of order, or what it means. Also, FDA lacks a comprehensive quality control program to independently evaluate and critique the adequacy of the reviewed submissions.

Additionally, FDA does not have a management information system that tracks individual reviewer workload and productivity. Further, FDA has not established adequate controls and written policies and procedures restricting industry access to section 510(k) medical device reviewers, safeguarding submission files, and assuring that there is physical security of its reviewing office.

Finally, as the FDA does not use certain critical information to make determinations of substantial equivalence, such as review of the product sample, verification of testing data, and premarket inspections of manufacturing facilities.

The former Commissioner of FDA put it very well. Dr. Frank Young had said this whole section 510(k) process is operating to a great measure on the Scout's honor system. We have certainly found when we looked at the generic drug division, which is very similar in operation to the section 510(k) process, that the Scout's honor system didn't work.

Many of the vulnerabilities we found in section 510(k) were also encountered in the generic drug division.

The one big significant difference, we have not found evidence that this has led to fraud or corruption of the section 510(k) process, but the vulnerabilities are there. We have been working with FDA to correct those systems and are working very hard on doing that, and we plan to have followup reviews to ensure they address each of these concerns.

With regard to postmarket surveillance, most device problems surface after the device is on the market, for a variety of reasons. Some problems you cannot anticipate, even in the premarket approval process, but then again, some of it may not be recognizable on the front end side, because it goes back to the Scout's honor system, and maybe they weren't Scouts after all.

FDA's postmarket surveillance activities include good manufacturing practices, inspections to assess and assure compliance with GMP regulations. They also have two problem reporting systems, the medical device and laboratory problem reporting program, the so-called PRP, a voluntary system for health care professionals, and the medical device reporting or MDR, a mandatory system for device manufacturers.

Recalls are an important postmarket activity. Most recalls are voluntary, whereby the firm removes or corrects marketed products. However, there is no requirement for the firm to notify FDA.

Although FDA has issued guidelines on policies, procedures, and industry responsibilities for recalls, they are not legally binding.

With regards to the significant weaknesses that we have found in the postmarket surveillance systems, we have approached it as we have other areas of FDA, trying to look from within, by examining the internal control systems, but then in fairness, also trying to approach it from the perspective of the manufacturers.

Most of the manufacturers we contacted in our survey consider FDA's staff competent, knowledgeable and fair, but, nevertheless we found the weaknesses exist in the postmarket activities and regulations.

There are six such weaknesses that I will highlight this morning. First is that FDA is unable to meet all its regulatory requirements for GMP and other types of inspections primarily because of limited resources.

Second, the MDR regulation is unclear, particularly the definition of serious injury and malfunction, and in some cases, the MDR system does not provide early warning of device problems.

Third, some regulatory actions take too much time and result in defective products remaining on the market far too long.

Fourth, most problems leading to recalls were related to device design, indicating the need for preproduction quality assurance regulations of some sort.

Fifth, mandatory notification of recalls may expedite the process, and FDA and manufacturers agree. The existing statute limits FDA's ability to find out about manufacturers' recalls or initiate its own efforts along that line.

Finally, some manufacturers themselves attribute device problems to user error, but in some cases, FDA may require design modifications to prevent problems with user errors.

In drawing these conclusions, we have reviewed individual case studies, and I would like to summarize a few of these, with more detailed recounting of them are in my prepared testimony.

We looked at the difibrillator-cardiac monitor, the device system worked well. The FDA became aware of a problem during the GMP inspection, and even though recalls are voluntary, FDA was able to convince the firm that a recall was warranted.

In the pacemaker lead we found that FDA could have taken a more aggressive and timely action by classifying the recall as class 1 immediately, and requesting a recall of all the lead models. This would have alerted physicians sooner.

With regards to the balloon dilation catheter, a lead from one of the firm's competitors led FDA to undisclosed recalls, failure to comply with MDR regulations, marketing without PMA, and ultimately, seizure of the product.

With regard to the spinal fixation system, FDA took aggressive action against this firm that violated the law and regulations. The firm had promoted and marketed a device for an unapproved use.

With regards to heart valves, we found that sometimes FDA has to pressure firms to recall products. In this case FDA threatened to withdraw premarket approval if the manufacturer did not initiate a recall on its own.

With regards to the kidney lithotripter, we found that user error as well as problems with the design of a device, can lead to injuries

and death. Even though the firm claimed that user errors led to the problem, FDA required the firm to modify the design.

With regards to the balloon inflation device, there were design defects which were not identified during the premarket testing or review, and ultimately led to recall. The firm officials suggested that FDA's preproduction quality assurance recommendations be incorporated into GMP regulations.

With regards to insulin infusion pumps, because GMP inspections concentrate on the manufacturer's major products and the manufacturer did not comply with MDR regulations, FDA was unaware of the severity of the problems with insulin pump until the district office conducted a recall inspection.

With regards to the microprocessor ventilator, the district office recommended an injunction because of repeated GMP violations. The FDA disapproved the recommendation, suggesting a notice of adverse findings instead.

With regard to the hemoperfusion device, the district referred an inspection report to FDA for an assessment and regulatory followup decision, but no followup occurred with FDA. Some actions, in fact, get buried in the mounds of paperwork that they have at FDA.

With the plasmapheresis equipment, the firm corrected the device defects, but did not notify FDA. After a complaint was received, it took FDA more than 9 months to take action, and more than 7 months to inform the firm to revise the product labels.

We have made some recommendations, Mr. Chairman, and many of these recommendations coincide with our initial review of your proposed legislation.

First, we have recommended that to improve controls over the premarket notification the FDA should implement its plan to redesign the management information system to capture and analyze workload and productivity information at the individual reviewer level, and to detect possible manipulation of the system.

This is the kind of thing we did find at FDA in the Generic Drug Division, which made it possible for certain of the crimes, which we prosecuted there to occur.

We also recommend that FDA document the first-in, first-out, first-review type of philosophy. That is reviewing the section 510(k) submissions in sequencing for delineating acceptable exceptions to the policy, and requiring documentation in the submission file when the policy is not used, to ensure the policy is uniformly applied to all reviewers.

We also believe FDA should determine whether current preferential treatment policy for expediting certain reviews of the section 510(k) process is really appropriate.

Also, FDA needs to continue to implement documentation format of the section 510(k) reviews.

FDA needs to augment the premarket notification process by designing a program for selectively testing devices, validating test results submitted in the section 510(k) system, and conducting premarket inspections of manufacturing facilities.

Also, FDA should establish a quality control review system that independently reviews premarket notification review decisions. And, finally, FDA should expedite implementation of controls re-

lated to employee-industry contact, develop written policies, procedures, to restrict these contacts, and to safeguard submission files in implementing physical security mechanisms.

With regards to postmarket surveillance activities of FDA, I can summarize by saying, as we look across all the work we have done, that FDA really needs to have some additional tools where they can intervene more quickly. They need to find timely and flexible mechanisms so they can intervene on behalf of public interest.

We also have recommended that the FDA should develop alternative strategies, such as changing user fees, to obtain the resources necessary to meet all of its regulatory requirements.

FDA also needs to clarify the MDR regulations, particularly of definitions of serious injury and malfunction.

Mr. WAXMAN. I am going to interrupt you because we have to move on. We will have the rest of that statement in the record. It is a very helpful, thorough analysis for us, and I appreciate it very much. I will have some questions of you in a minute.

[Testimony resumes on p. 106.]

[The prepared statement of Mr. Kusserow follows:]

TESTIMONY

OF

RICHARD P. KUSSEROW

INSPECTOR GENERAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

GOOD MORNING, MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE. I AM RICHARD P. KUSSEROW, INSPECTOR GENERAL FOR THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS). WE ARE HERE THIS MORNING, AT YOUR REQUEST, TO SHARE WITH YOU THE RESULTS OF OUR REVIEWS OF THE FOOD AND DRUG ADMINISTRATION'S (FDA) REGULATORY PROCESS FOR PREMARKET REVIEW AND POSTMARKET SURVEILLANCE OF MEDICAL DEVICES.

INTRODUCTION

AS YOU KNOW, THE OFFICE OF INSPECTOR GENERAL (OIG) HAS BEEN HEAVILY INVOLVED IN CONDUCTING OVERSIGHT AUDITS, INSPECTIONS AND INVESTIGATIONS THROUGHOUT FDA. MOST OF OUR REVIEWS HAVE BEEN AT THE REQUEST OF THE COMMISSIONER OF FDA, CONSISTENT WITH THE AGENCY'S ONGOING COMMITMENT TO IMPROVE THEIR EFFICIENCY, EFFECTIVENESS AND INTEGRITY.

AS PART OF OUR ONGOING OVERSIGHT REVIEWS OF FDA'S REGULATORY PROGRAMS WE HAVE BEEN EXAMINING THE MEDICAL DEVICE REGULATORY SYSTEM. OUR WORK TO DATE HAS IDENTIFIED SOME WEAKNESSES IN BOTH THE PREMARKET REVIEW AS WELL AS POSTMARKET SURVEILLANCE SYSTEMS FOR MEDICAL DEVICES. IN THE PREMARKET REVIEW SYSTEM WE FOUND INTERNAL CONTROL WEAKNESSES WHICH RAISE QUESTIONS ABOUT THE PROCESS AND WHETHER IT ENSURES THAT DEVICE MANUFACTURERS ARE TREATED FAIRLY AND WHETHER THE DEVICES REVIEWED ARE SUBSTANTIALLY EQUIVALENT. IN THE POSTMARKET SURVEILLANCE SYSTEM WE FOUND FLAWS IN THE REGULATORY SYSTEM WHICH MAY PREVENT FDA FROM DETECTING DEVICE PROBLEMS EARLY

ON AND TAKING PROMPT ACTION, LEAVING DEFECTIVE PRODUCTS ON THE MARKET LONGER THAN NECESSARY.

WITH YOUR PERMISSION, I WOULD LIKE TO MAKE COPIES OF THE FOLLOWING OIG REPORTS A PART OF THE RECORD OF TODAY'S HEARING: "INTERNAL CONTROL WEAKNESSES IN THE FOOD AND DRUG ADMINISTRATION'S MEDICAL DEVICE 510(K) REVIEW PROCESS," "REVIEW OF THE FOOD AND DRUG ADMINISTRATION'S ACTIONS RELATIVE TO THE RECALL OF THE MEDTRONIC MODEL 6972 PACEMAKER LEAD," "REVIEW OF ALLEGATIONS MADE BY CLARK RESEARCH AND DEVELOPMENT, INCORPORATED AGAINST THE FOOD AND DRUG ADMINISTRATION," "REVIEW OF ALLEGATIONS OF DEFECTIVE PLASMAPHERESIS EQUIPMENT REGULATED BY THE FOOD AND DRUG ADMINISTRATION," AND "ISSUES RELATED TO THE FOOD AND DRUG ADMINISTRATION'S REGULATION OF HEMOPERFUSION MEDICAL DEVICES." ADDITIONALLY, WE WILL SOON BE RELEASING A DRAFT REPORT, "FDA MEDICAL DEVICE REGULATION FROM PREMARKET REVIEW TO RECALL," AND WILL MAKE A COPY AVAILABLE TO THE SUBCOMMITTEE AT THAT TIME.

PERMIT ME TO BEGIN WITH THE FRONT-END OF THE SYSTEM OR PREMARKET REVIEW, AND THEN FINISH WITH THE SYSTEM'S BACK-END, OR POSTMARKET SURVEILLANCE ACTIVITIES.

PREMARKET REVIEW

MEDICAL DEVICES PLAY A VITAL ROLE IN HEALTH CARE DELIVERY TODAY. TECHNOLOGICAL ADVANCES IN MEDICAL DEVICES HAVE REVOLUTIONIZED

MEDICAL TREATMENT. MEDICAL DEVICES RANGE FROM THE SIMPLE, SUCH AS TONGUE DEPRESSORS, TO THE COMPLEX, SUCH AS ARTIFICIAL HEARTS. BEFORE 1976, MEDICAL DEVICES WERE LARGELY UNREGULATED. RESPONDING TO INCREASING PUBLIC CONCERN ABOUT THE SAFETY AND EFFECTIVENESS OF MEDICAL DEVICES DURING THE LATE 1960'S AND EARLY 1970'S, CONGRESS PASSED THE 1976 MEDICAL DEVICE AMENDMENTS TO THE FOOD, DRUG AND COSMETIC ACT (THE ACT). THE AMENDMENTS PROVIDE A SET OF REGULATORY CONTROLS FOR THE MARKETING OF MEDICAL DEVICES TO CURB ABUSES AND TO PROTECT THE AMERICAN PUBLIC.

THE 1976 AMENDMENTS CREATED THREE CLASSES OF DEVICES, WHICH ARE DISTINGUISHED BY THE EXTENT OF REGULATION REQUIRED. CLASS I DEVICES, SUCH AS THERMOMETERS AND STETHOSCOPES, ARE SUBJECT TO GENERAL CONTROLS SUCH AS PROHIBITIONS AGAINST MISBRANDING. CLASS II DEVICES, SUCH AS HEARING AIDS AND GLUCOSE MONITORS, ARE SUBJECT TO GENERAL CONTROLS AND PERFORMANCE STANDARDS. CLASS III DEVICES, SUCH AS PACEMAKERS AND HEART VALVES, MUST UNDERGO PREMARKET APPROVAL (PMA), A RIGOROUS REVIEW PROCESS, IN ORDER TO BE PROVEN SAFE AND EFFECTIVE.

THE 1976 AMENDMENTS REQUIRES MANUFACTURERS TO NOTIFY FDA OF THEIR INTENT TO MARKET A NEW MEDICAL DEVICE. SECTION 510(K) OF THE ACT REQUIRES THAT 90 DAYS PRIOR TO MARKETING A DEVICE, THE MANUFACTURER MUST INFORM FDA OF ITS INTENT. ALL NEW DEVICES SUBMITTED TO FDA FOR REVIEW ARE PLACED AUTOMATICALLY INTO CLASS III AND ARE THEREFORE SUBJECT TO PMA UNLESS THE MANUFACTURER CONTENDS THAT THE

DEVICE IS "SUBSTANTIALLY EQUIVALENT" TO (1) ANY DEVICE MARKETED BEFORE MAY 28, 1976, OR TO (2) A DEVICE MARKETED AFTER THAT DATE THAT IS CLASSIFIED IN CLASS I OR CLASS II. IF FDA CONCURS, THE DEVICE BECOMES SUBJECT TO THE SAME REQUIREMENTS AS ITS PREDECESSOR. IF FDA DETERMINES THAT A DEVICE IS SUBSTANTIALLY EQUIVALENT TO A CLASS I, CLASS II OR PRE-1976 DEVICE, THE DEVICE CAN ENTER THE MARKET WITH ONLY THE 510(K) NOTIFICATION. THE 510(K) PROCESS HAS THE EFFECT OF "GRANDFATHERING" THE DEVICE WITHOUT THE MORE PROTRACTED REVIEW PROCESS. IF THE DEVICE DOES NOT MEET THE TEST UNDER 510(K), IT MUST UNDERGO THE FULL PMA PROCESS.

UNLIKE THE ABBREVIATED 510(K) NOTIFICATION PROCESS, THE PMA REVIEW PROCESS INVOLVES AN IN-DEPTH SCIENTIFIC REVIEW TO ENSURE THE SAFETY AND EFFECTIVENESS OF THE DEVICE. MANUFACTURERS SUBMITTING A PMA APPLICATION MUST PROVIDE DATA FROM CLINICAL TRIALS AND OTHER SOURCES DEMONSTRATING THE SAFETY AND EFFECTIVENESS OF THE DEVICE. BEFORE CONDUCTING A CLINICAL TRIAL, FIRMS MUST SUBMIT AN INVESTIGATIONAL DEVICE EXEMPTION (IDE) APPLICATION. THE IDE PROGRAM IS DESIGNED TO PROTECT THE SAFETY AND RIGHTS OF PATIENTS.

CURRENTLY, MOST DEVICES REACH THE MARKET THROUGH THE 510(K) PROCESS. FROM 1976 THROUGH 1988, APPROXIMATELY 94 PERCENT OF MORE THAN 36,000 DEVICES AND DEVICE MODIFICATIONS CURRENTLY IN USE ENTERED THE MARKET AFTER THE FDA DETERMINED THAT THE PRODUCTS WERE SUBSTANTIALLY EQUIVALENT TO DEVICES ALREADY ON THE MARKET. ONLY

SIX PERCENT OF THE DEVICES ENTERED THROUGH THE RIGOROUS PMA PROCESS DEMONSTRATING SAFETY AND EFFECTIVENESS.

INTERNAL CONTROL WEAKNESSES IN THE FDA 510(K) REVIEW PROCESS

OUR REVIEW OF THE 510(K) PROCESS FOUND MATERIAL WEAKNESSES WHICH COULD IMPAIR FDA'S MISSION OF ASSURING A FAIR PREMARKET NOTIFICATION PROCESS AND NEGATIVELY AFFECT THE PUBLIC'S CONFIDENCE IN FDA'S ABILITY TO PROTECT THE PUBLIC HEALTH. MOST OF OUR FINDINGS HERE PARALLEL WHAT WE ENCOUNTERED IN OUR EXTENSIVE REVIEWS OF THE GENERIC DRUG DIVISION. IN THAT CASE THE VULNERABILITIES HAD RESULTED IN INSTANCES OF FRAUD AND CORRUPTION. ALTHOUGH OUR FINDINGS HERE ARE SIMILAR, WE HAVE NO EVIDENCE OF THESE VULNERABILITIES MANIFESTING THEMSELVES IN ANY DETECTED CRIMINAL WRONGDOING. THE FIVE MOST SIGNIFICANT FINDINGS OF OUR REVIEW OF THE 510(K) PROCESS WERE:

(1) THE FDA LACKS WRITTEN POLICIES AND PROCEDURES FOR SEQUENCING 510(K) REVIEWS AND DOCUMENTING REVIEW DECISIONS TO ENSURE TIMELY, FAIR AND COMPLETE 510(K) EVALUATIONS. ALTHOUGH FDA HAS ESTABLISHED WRITTEN GUIDANCE FOR REVIEWERS TO USE IN DETERMINING SUBSTANTIAL EQUIVALENCE, THOROUGH WRITTEN DOCUMENTATION OF THE REVIEW IS NOT YET REQUIRED TO BE INCLUDED IN ALL FILES. THE FDA IS ACTING UPON OUR FINDINGS AND RECOMMENDATIONS AND IS IN THE PROCESS OF DEVELOPING A DOCUMENTATION FORMAT THAT WILL GREATLY REDUCE THIS VULNERABILITY.

(2) THE FDA LACKS A COMPREHENSIVE QUALITY CONTROL PROGRAM TO INDEPENDENTLY EVALUATE AND CRITIQUE THE ADEQUACY OF REVIEWED SUBMISSIONS. THE FDA RELIES ON THE SUPERVISORY REVIEW PROCESS AND HAS NO INDEPENDENT ASSESSMENT TO DETERMINE IF SUPERVISORS AND REVIEWERS ARE FOLLOWING APPROPRIATE PROCEDURES AND MAKING SOUND RECOMMENDATIONS REGARDING SUBSTANTIAL EQUIVALENCE DETERMINATIONS.

(3) THE FDA DOES NOT HAVE A MANAGEMENT INFORMATION SYSTEM THAT TRACKS INDIVIDUAL REVIEWER WORKLOAD AND PRODUCTIVITY. CONSEQUENTLY, THERE IS NO MEANS TO DETERMINE PRODUCTIVITY VARIANCES AMONG REVIEWERS OR IF THE PRODUCTIVITY VARIANCES DO OCCUR WHAT THE REASONS ARE. FURTHERMORE, THIS INABILITY TO MONITOR CREATES A VULNERABILITY FOR SOMEONE TO MANIPULATE THE PROCESS. A MANAGEMENT INFORMATION SYSTEM IS AN ESSENTIAL AND INTEGRAL COMPONENT OF A COMPREHENSIVE QUALITY CONTROL PROGRAM.

(4) THE FDA HAS NOT ESTABLISHED ADEQUATE CONTROLS AND WRITTEN POLICIES AND PROCEDURES RESTRICTING INDUSTRY ACCESS TO 510(K) MEDICAL DEVICE REVIEWERS, SAFEGUARDING SUBMISSION FILES, AND ASSURING THE PHYSICAL SECURITY OF ITS REVIEWING OFFICES. NO WRITTEN POLICY EXISTS REGARDING FDA STAFF CONTACTS WITH INDUSTRY REPRESENTATIVES TO ASSURE THAT SUCH CONTACTS ARE APPROPRIATELY CONDUCTED AND DOCUMENTED SO AS TO LIMIT IMPROPER INFLUENCING OF THE PROCESS.

(5) THE FDA DOES NOT USE CERTAIN CRITICAL INFORMATION TO MAKE DETERMINATIONS OF SUBSTANTIAL EQUIVALENCE, SUCH AS REVIEW OF THE PRODUCT SAMPLE OR VERIFICATION OF TESTING DATA, AND PREMARKET INSPECTIONS OF MANUFACTURER FACILITIES. THE FDA DOES NOT REQUIRE TESTING OF THE DEVICE DURING THE 510(K) PROCESS. SUCH TESTING, WHICH IS NOT PRECLUDED IN THE ACT OR IN THE REGULATIONS, WOULD PROVIDE ADDED ASSURANCE OF THE DEVICE'S SUBSTANTIAL EQUIVALENCY AND IDENTIFY THE SUBMISSION OF FRAUDULENT DATA. SINCE TESTING DATA SUBMITTED BY MANUFACTURERS IS NOT VERIFIED, THIS IS ESPECIALLY IMPORTANT. FDA'S RELIANCE UPON THE "HONOR SYSTEM" DOES NOT PROVIDE ADEQUATE SAFEGUARDS.

THE FDA DOES NOT CONDUCT INSPECTIONS OF MEDICAL DEVICE MANUFACTURERS IN CONJUNCTION WITH THE SUBSTANTIAL EQUIVALENCE DECISION-MAKING PROCESS OR PRIOR TO THE DEVICE BEING MARKETED. INSPECTIONS ARE ONLY CONDUCTED AS PART OF THE POSTMARKET SURVEILLANCE OPERATIONS. CURRENTLY, ONLY A WEAK LINK EXISTS BETWEEN THE PREMARKET NOTIFICATION PROCESS AND THE POSTMARKET ACTIVITIES. THE FIRM'S REGULATORY HISTORY IS NOT USUALLY CONSIDERED DURING PREMARKET REVIEW, WITH THE EXCEPTION OF A RECENT GUIDANCE WHICH SPECIFIES THAT FOR STERILE PRODUCTS FDA SHOULD REVIEW ITS DATA BASE TO DETERMINE A FIRM'S REGULATORY HISTORY. INFORMATION ABOUT THE MANUFACTURER'S POSTMARKET RECORD IS IMPORTANT FOR ALL TYPES OF DEVICES. OUTSTANDING COMPLIANCE PROBLEMS COULD HAVE CONSEQUENCES FOR THE DEVICE UNDER REVIEW.

MANY OF THE WEAKNESSES WE FOUND IN THE 510(K) PROCESS WERE ALSO NOTED IN FDA'S RECENTLY COMPLETED INTERNAL CONTROL REVIEW. HOWEVER, THE FDA DID NOT ADDRESS CERTAIN AREAS THAT WE EXAMINED DURING OUR REVIEW, SUCH AS TESTING, INSPECTION INFORMATION AND QUALITY CONTROL. THE FDA INFORMED US THAT THEY HAVE DEVELOPED A CORRECTIVE ACTION PLAN WHICH ADDRESSES EACH OF THE WEAKNESSES IDENTIFIED DURING FDA'S OWN INTERNAL REVIEW. WE ARE AWAITING A CORRECTIVE ACTION PLAN FROM FDA IN RESPONSE TO THE OIG FINAL REPORT ON THE 510(K) PROCESS.

NOW LET'S MOVE ON TO THE POSTMARKET SURVEILLANCE ACTIVITIES.

POSTMARKET SURVEILLANCE

MANY QUESTIONS ABOUT A DEVICE'S SAFETY AND EFFECTIVENESS ARE NOT IDENTIFIED UNTIL AFTER A DEVICE IS MARKETED AND USED IN THE GENERAL POPULATION. FOR THIS REASON IT IS CRITICAL TO HAVE AN EFFECTIVE SYSTEM IN PLACE TO DETECT PROBLEMS AND TO TAKE PROMPT REGULATORY ACTIONS AGAINST VIOLATIVE FIRMS WHEN NECESSARY. FDA'S POSTMARKET SURVEILLANCE ACTIVITIES INCLUDE THE FOLLOWING:

GOOD MANUFACTURING PRACTICES (GMP) INSPECTIONS THE FDA INSPECTS MANUFACTURERS TO ASSESS COMPLIANCE WITH THE GMP REGULATION, WHICH REQUIRES THAT MANUFACTURERS HAVE A QUALITY ASSURANCE PROGRAM. WHEN DISTRICTS IDENTIFY GMP DEVIATIONS, THEY CAN TAKE REGULATORY ACTION IF A FIRM DOES NOT ATTEMPT TO CORRECT THE PROBLEMS. SUCH ACTIONS

INCLUDE ISSUING A NOTICE OF ADVERSE FINDINGS OR A REGULATORY LETTER TO THE FIRM, OR WHEN WARRANTED, INITIATING INJUNCTIONS, SEIZURES OR CRIMINAL PROSECUTIONS.

PROBLEM REPORTING THE FDA HAS TWO REPORTING SYSTEMS TO ALERT IT TO DEVICE PROBLEMS. THEY ARE INTENDED TO PROVIDE EARLY WARNING TO THE FDA ABOUT PROBLEMS ASSOCIATED WITH DEVICES IN USE. ONE IS A VOLUNTARY SYSTEM FOR HEALTH CARE PROFESSIONALS, THE MEDICAL DEVICE AND LABORATORY PROBLEM REPORTING PROGRAM (PRP) SYSTEM. THE OTHER SYSTEM IS THE MANDATORY MEDICAL DEVICE REPORTING (MDR) SYSTEM. MANUFACTURERS ARE REQUIRED TO SUBMIT MDR REPORTS ABOUT ANY DEVICE-RELATED DEATHS OR SERIOUS INJURIES, OR ANY DEVICE MALFUNCTION WHICH MIGHT CONTRIBUTE TO A DEATH OR A SERIOUS INJURY. THE FDA ASSESSES MANUFACTURER'S COMPLIANCE WITH THE MDR REGULATION DURING GMP INSPECTIONS.

RECALLS A RECALL IS DEFINED AS A FIRM'S REMOVAL OR CORRECTION OF A MARKETED PRODUCT THAT IS IN VIOLATION OF THE ACT. RECALLS ARE MOSTLY VOLUNTARY. THE STATUTE DOES EMPOWER FDA TO RECALL A DEVICE. HOWEVER, THE CRITERIA FOR ITS USE ARE SO RESTRICTIVE AS TO BE IMPRACTICAL. ADDITIONALLY, THE FDA CAN REQUEST THAT THE FIRM INITIATE A RECALL IN AN URGENT SITUATION. NEVERTHELESS, THE FDA CANNOT REQUIRE THAT A FIRM REPORT A VOLUNTARY RECALL TO FDA.

THE FDA GUIDELINES SUGGEST THAT WHEN A FIRM INITIATES A RECALL, IT SHOULD NOTIFY THE APPROPRIATE FDA DISTRICT OFFICE. WHEN FDA

RECEIVES A RECALL REPORT, THE DISTRICT OFFICE CONDUCTS AN INSPECTION TO GATHER INFORMATION ABOUT THE RECALL AND SENDS A RECALL RECOMMENDATION TO FDA. THE FDA EVALUATES THE ASSOCIATED HEALTH HAZARD AND CLASSIFIES THE RECALL ACCORDING TO THE RELATIVE DEGREE OF RISK. A CLASS I RECALL INDICATES THE DEVICE MAY CAUSE SERIOUS, ADVERSE HEALTH CONSEQUENCES OR DEATH. A CLASS II RECALL INDICATES THE DEVICE MAY CAUSE TEMPORARY OR MEDICALLY REVERSIBLE ADVERSE HEALTH CONSEQUENCES. A CLASS III RECALL INDICATES THE DEVICE IS NOT LIKELY TO CAUSE ADVERSE HEALTH CONSEQUENCES. THE FDA PUBLISHES A LIST OF RECALLS IN ITS WEEKLY FDA ENFORCEMENT REPORT.

WEAKNESSES IN THE POSTMARKET SURVEILLANCE SYSTEMS

OUR STUDY OF POSTMARKET SURVEILLANCE SYSTEMS FOUND THAT MOST MANUFACTURERS CONSIDER FDA STAFF COMPETENT, KNOWLEDGEABLE AND FAIR. NEVERTHELESS, WE FOUND WEAKNESSES IN THE POSTMARKET ACTIVITIES AND THE REGULATORY SYSTEMS. THE SIX MOST SIGNIFICANT FINDINGS OF OUR REVIEW OF THE POSTMARKET SURVEILLANCE WERE:

(1) THE FDA IS UNABLE TO MEET ALL OF ITS STATUTORY AND REGULATORY REQUIREMENTS FOR GMP AND OTHER TYPES OF INSPECTIONS, PRIMARILY BECAUSE OF LIMITED RESOURCES. INSPECTIONS ARE VERY RESOURCE INTENSIVE AND TAKE UP A LOT OF STAFF TIME. DISTRICT OFFICES INDICATED THAT NUMEROUS HIGH PRIORITY ASSIGNMENTS CONSUME THEIR LIMITED RESOURCES AND, CONSEQUENTLY, ROUTINE INSPECTIONS AND

ACTIVITIES ARE SOMETIMES DELAYED. ADDITIONALLY, INSPECTORS NEED MORE TRAINING TO ADEQUATELY INSPECT DEVICE FIRMS AND FDA NEEDS MORE AND BETTER EQUIPMENT.

THE FDA IS AWARE THAT THE DISTRICTS ARE NOT MEETING THE BIENNIAL GMP INSPECTION REQUIREMENT. FDA'S DATA INDICATES THAT 51 PERCENT OF ALL FIRMS WERE NOT INSPECTED IN CONFORMANCE WITH THE BIENNIAL REQUIREMENT. FURTHER, AS OF AUGUST 1988, 19 PERCENT OF CLASS I AND II DEVICE FIRMS HAD NEVER BEEN INSPECTED.

(2) THE MDR REGULATION IS UNCLEAR, PARTICULARLY THE DEFINITION OF SERIOUS INJURY AND MALFUNCTION, AND DOES NOT ALWAYS PROVIDE EARLY WARNING ABOUT DEVICE PROBLEMS. BOTH MANUFACTURERS AND FDA AGREE THAT THE MDR REGULATION IS VAGUE AND SUBJECT TO INTERPRETATION. SEVERAL CASES WE EXAMINED INDICATED PROBLEMS WITH THE INTERPRETATION OF THE REGULATION AS WELL. IN THESE CASES THE FIRMS HAD NOT NOTIFIED FDA OF MANY REPORTABLE EVENTS AND CONSEQUENTLY FDA WAS NOT ABLE TO TAKE PROMPT ACTION. FURTHER, THE VOLUNTARY PROBLEM REPORTING PROGRAM IS UNDERUSED AND DOES NOT PROVIDE THE FDA WITH ADEQUATE OR MEANINGFUL INFORMATION.

(3) SOME REGULATORY ACTIONS TAKE TOO MUCH TIME AND RESULT IN DEFECTIVE PRODUCTS REMAINING ON THE MARKET TOO LONG. IN ONE CASE THE SEIZURE PROCESS TOOK MORE THAN 5 MONTHS FROM THE INITIAL DISTRICT OFFICE REVIEW THROUGH THE SEIZURE. IN ANOTHER CASE, AN

IDE WITHDRAWAL TOOK SEVERAL MONTHS AND A RECOMMENDATION FOR AN INJUNCTION MADE IN OCTOBER 1989 IS STILL PENDING.

(4) MOST PROBLEMS LEADING TO RECALLS WERE RELATED TO THE DEVICE'S DESIGN. IN VIRTUALLY ALL OF THE CASES WE REVIEWED DESIGN PROBLEMS LED TO THE RECALLS. THE FDA HAS DETERMINED THAT DESIGN PROBLEMS ARE THE LEADING CAUSE OF DEVICE RECALLS. FORTY-FOUR PERCENT OF ALL QUALITY PROBLEMS RESULTING IN RECALLS FROM 1983 TO 1988 WERE ATTRIBUTABLE TO PREPRODUCTION OR DESIGN DEFICIENCIES.

TO ADDRESS THIS PROBLEM, FDA HAS ISSUED PREPRODUCTION QUALITY ASSURANCE (PPQA) RECOMMENDATIONS FOR MEDICAL DEVICE MANUFACTURERS. HOWEVER, THESE RECOMMENDATIONS ARE NOT LEGALLY BINDING. OUR CASES ILLUSTRATE THE NEED TO INCORPORATE THE PPQA RECOMMENDATIONS INTO THE GMP REGULATION. IN FACT, ONE COMPANY OFFICIAL SUGGESTED THAT THE PPQA RECOMMENDATIONS SHOULD BE INCLUDED IN THE GMP REGULATION.

(5) MANDATORY NOTIFICATION OF RECALLS MAY EXPEDITE THE PROCESS. SOME DISTRICTS AND MANUFACTURERS VOLUNTEERED THAT MANDATORY NOTIFICATION IS WARRANTED. THEY BELIEVE IT IS A GOOD PRACTICE TO KEEP FDA INFORMED IN ORDER TO AVOID AFTER-THE-FACT RECALLS. THE CASES WE REVIEWED ILLUSTRATE HOW IMPORTANT IT IS FOR FDA TO MONITOR THE FIRM'S RECALL STRATEGY.

THE EXISTING STATUTE LIMITS FDA'S ABILITY TO FIND OUT ABOUT MANUFACTURERS' RECALLS OR INITIATE ITS OWN CORRECTIVE ACTIONS FOR

DEVICE PROBLEMS. FDA NEEDS SPECIFIC AUTHORITY SO THAT IT CAN TAKE PROMPT ACTION TO CORRECT OR REMOVE MEDICAL DEVICES THAT POSE PUBLIC HEALTH RISKS.

(6) SOME MANUFACTURERS ATTRIBUTED DEVICE PROBLEMS TO USER ERROR. FDA CONDUCTS EDUCATIONAL ACTIVITIES IN NUMEROUS PROGRAM AREAS TO ADDRESS THE PROBLEM OF USER ERROR. FDA ALSO PERFORMS SCIENTIFIC ANALYSIS TO DETERMINE WHY DEVICES FAIL AND REQUESTS THAT MANUFACTURERS MODIFY DESIGNS TO PREVENT PROBLEMS WITH USER ERROR. BUT SOME MANUFACTURER'S SUGGEST THAT FDA COULD BE EVEN MORE ACTIVE IN EDUCATING USERS AND CONSUMERS ABOUT MEDICAL DEVICES.

CASE STUDY EXAMPLES

AS YOU REQUESTED MR. CHAIRMAN, OUR STUDY OF THE REGULATION OF MEDICAL DEVICES USED A CASE STUDY APPROACH. THE FOLLOWING CASE STUDIES ILLUSTRATE THE STRENGTHS AND WEAKNESSES, ALREADY DESCRIBED, IN FDA'S REGULATORY SYSTEM FOR MEDICAL DEVICES. FOR EACH CASE STUDY WE HAVE DESCRIBED THE DEVICE AND THE DEFECT AND SUMMARIZED THE SIGNIFICANT ISSUES THAT EMERGED IN THE CASE.

DEFIBRILLATOR/CARDIAC MONITOR

DEFIBRILLATORS ARE ELECTRONIC DEVICES THAT ARE USED TO PROVIDE BRIEF ELECTRICAL SHOCK TO THE HEART TO RESTORE THE NORMAL HEART RHYTHM. THE FDA LEARNED THAT THE CARDIAC MONITOR REGISTERED A

'FLAT LINE' (NO HEART BEAT) WHEN A SPECIFIC ADAPTER WAS USED AT VARIOUS FREQUENCIES FOLLOWING A DEFIBRILLATOR DISCHARGE OF GREATER THAN 200 JOULES. ESSENTIALLY, THE STRAP WAS USED TO PROVIDE ELECTRICAL POWER TO BOTH THE DEFIBRILLATOR AND MONITOR THROUGH A SINGLE LINE CORD. FDA IDENTIFIED THE PROBLEM WITH THIS DEVICE DURING A ROUTINE GMP INSPECTION AND LEARNED THAT THE MANUFACTURER DID NOT PLAN TO NOTIFY CUSTOMERS ABOUT IT. THE FIRM ULTIMATELY AGREED TO RECALL THE DEFECTIVE PRODUCT.

IN THIS CASE THE SYSTEM WORKED WELL. THE FDA BECAME AWARE OF THE PROBLEM DURING A ROUTINE INSPECTION AND EVEN THOUGH RECALLS ARE VOLUNTARY, FDA WAS ABLE TO CONVINCE THE FIRM THAT A RECALL WAS WARRANTED.

PACEMAKER LEAD

THE PACEMAKER SYSTEM, WHICH IS IMPLANTED INTO THE BODY OF A PATIENT, CONSISTS OF A POWER SOURCE OR PULSE GENERATOR, COMMONLY CALLED A PACEMAKER, AND A LEAD WIRE WHICH TRANSMITS THE PERIODIC ELECTRICAL IMPULSE TO THE HEART. IN FEBRUARY 1984, THIS FIRM ISSUED LETTERS TO THOUSANDS OF PHYSICIANS ADVISING THEM OF THE INCREASED FAILURE RATE OF THE BIPOLAR LEAD IN ONE OF ITS MODELS. THIS MODEL, MANUFACTURED BETWEEN 1979 AND 1982, HAD A HIGHER INCIDENCE OF FAILURE THAN OTHER MODELS AND WAS MORE SUSCEPTIBLE TO INSULATION DAMAGE. THE FIRM ESTIMATED THAT FOR THIS MODEL, OF THE

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26,721 LEADS SOLD IN THIS COUNTRY, 18,000 REMAINED IMPLANTED AS OF THE DATE OF THE LETTER.

ORIGINALLY THE FDA CLASSIFIED THIS ACTION AS A CLASS II RECALL. LATER, FDA REEVALUATED THE POTENTIAL HEALTH HAZARD AND CONCLUDED THAT THE ACTION BE RECLASSIFIED AS A CLASS I RECALL. FURTHER, FDA INSTRUCTED THE FIRM TO STOP MARKETING THE LEAD BECAUSE FDA BELIEVED THAT THE LEAD BEING MARKETED WAS NOT THE DEVICE FOUND TO BE SUBSTANTIALLY EQUIVALENT IN 1979.

THE FIRM SUBMITTED AN AMENDMENT TO ITS PREMARKET NOTICE INDICATING 31 DESIGN AND MANUFACTURING CHANGES SINCE 1979. FDA WAS CONCERNED THAT THE FIRM HAD NOT PERFORMED ANALYSIS OF THE CLINICAL FAILURES BEFORE MAKING THE CHANGES. AS A RESULT, THE FIRM VOLUNTARILY WITHDREW THE AMENDMENT AND EXPANDED ITS RECALL TO INCLUDE OTHER LEAD MODELS AS WELL.

IN THIS CASE, FDA COULD HAVE TAKEN MORE AGGRESSIVE AND TIMELY ACTION. FDA HAD THE CRUCIAL INFORMATION AND COULD HAVE CLASSIFIED THE RECALL AS A CLASS I IMMEDIATELY AND REQUESTED A RECALL OF ALL THE LEAD MODELS RATHER THAN ISSUING A CEASE MARKETING ORDER. THIS WOULD HAVE ALERTED PHYSICIANS SOONER TO THE CONCERNS ABOUT THE SAFETY OF THE LEADS.

BALLOON DILATION CATHETER

THE BALLOON DILATION CATHETER IS USED DURING THE ANGIOPLASTY PROCEDURE. IT CONSISTS OF A THIN-COATED STAINLESS STEEL TUBE, OR WIRE, WITH A BALLOON AT ONE END. DURING THE PROCEDURE, THE BALLOON IS INFLATED WHEN IT REACHES THE CLOGGED PORTION OF AN ARTERY. THE PURPOSE IS TO COMPRESS PLAQUE AGAINST THE ARTERY SO THAT BLOOD FLOW WILL INCREASE.

SINCE 1988 THE FIRM HAS RELEASED THREE MODELS OF THE CATHETER. THE FIRST CATHETER, WHICH HAD A PROBLEM WITH THE BALLOON WRAPPING AROUND THE WIRE, WAS REPLACED WITH A SECOND VERSION, AND ULTIMATELY WAS REPLACED WITH A THIRD VERSION BECAUSE OF NUMEROUS BROKEN CATHETER TIPS. THE FIRM DID NOT DESIGNATE THE TWO REPLACEMENTS AS RECALLS AND ALSO FAILED TO SUBMIT A PMA SUPPLEMENT FOR THE THIRD CATHETER. ALTHOUGH THE MANUFACTURER ATTRIBUTED THE PROBLEM TO USERS OVERROTATING THE CATHETER, THE FDA DETERMINED THAT THE DEVICE'S DESIGN WAS INADEQUATE TO PREVENT OVERROTATION.

IN THIS CASE A LEAD FROM ONE OF THIS FIRM'S COMPETITORS LED FDA TO UNDISCLOSED RECALLS, A FAILURE TO COMPLY WITH THE MDR REGULATION (THE FIRM FAILED TO SUBMIT OVER 200 MDRS), MARKETING WITHOUT PMA, AND ULTIMATELY, SEIZURE OF THIS MANUFACTURER'S PRODUCT. HOWEVER, THE SEIZURE PROCESS TOOK OVER 5 MONTHS FROM THE TIME OF THE INITIAL DISTRICT OFFICE REVIEW THROUGH THE SEIZURE.

BALLOON INFLATION DEVICE

THE BALLOON INFLATION DEVICE WAS INTENDED TO INFLATE, DEFLATE, AND MONITOR THE PRESSURE OF A BALLOON CATHETER, WHICH IS USED IN ANGIOPLASTY TO UNCLOG BLOCKED ARTERIES. FDA REVIEWED THE 510(K) FOR THIS DEVICE AND DETERMINED IT TO BE SUBSTANTIALLY EQUIVALENT. WITHIN DAYS OF THE DEVICE'S RELEASE, THE FIRM RECEIVED COMPLAINTS CONCERNING THE GAUGE, WHICH WAS STICKING, RESULTING IN INACCURATE PRESSURE READINGS. THIS COULD CAUSE A PHYSICIAN TO OVERINFLATE AND POSSIBLY BURST THE BALLOON. AFTER SEVERAL OTHER COMPLAINTS THE COMPANY DECIDED TO RECALL THE DEVICE.

IN THIS CASE, DESIGN DEFECTS WHICH LED TO A RECALL COULD HAVE BEEN DISCLOSED DURING PREMARKET TESTING. HOWEVER, THE FDA DID NOT VERIFY THE MANUFACTURER'S CLAIMS THAT THE GAUGE WOULD BE ACCURATE WITHIN A CERTAIN PERCENTAGE, SINCE THE 510(K) PROCEDURE DOES NOT REQUIRE FOR VERIFICATION OF TESTING DATA. FIRM OFFICIALS SAID THAT THEY COULD HAVE BENEFITED FROM A PILOT TEST BEFORE THEY WENT INTO MASS PRODUCTION. THEY SUGGESTED THAT FDA'S PREPRODUCTION QUALITY ASSURANCE RECOMMENDATIONS SHOULD BE INCORPORATED INTO THE GMP REGULATIONS.

SPINAL FIXATION SYSTEM

THIS FIRM SOUGHT SUBSTANTIAL EQUIVALENCE DETERMINATIONS FOR STAINLESS STEEL PLATES AND SCREWS THAT AN ORTHOPEDIC SURGEON HAD

DEVELOPED AND IMPLANTED IN PATIENTS VERTEBRAE. THE FDA DETERMINED THAT THE SPINAL FIXATION SYSTEM WAS NOT SUBSTANTIALLY EQUIVALENT AND THAT THE FIRM WOULD HAVE TO OBTAIN PREMARKET APPROVAL BEFORE MARKETING THE PRODUCT. THE FIRM SUBSEQUENTLY FILED A 510(K) TO USE THE PLATES AND SCREWS IN LONG BONES AND FLAT BONES, SUCH AS THE PELVIS, BUT NOT THE SPINE. THE FDA FOUND THE DEVICE SUBSTANTIALLY EQUIVALENT FOR THAT INTENDED USE.

DURING AN INSPECTION OF THIS FIRM, THE FDA FOUND TWO MAJOR VIOLATIONS RELATING TO THE PROMOTION AND DISTRIBUTION OF DEVICES THAT RESULTED FROM A FAILURE TO COMPLY WITH THE IDE REGULATION AND THE SALE AND USE OF DEVICES FOR AN UNINTENDED USE. THE FIRM WAS MARKETING THE PLATES AND SCREWS FOR USE IN THE SPINE. IN OCTOBER 1989, THE DISTRICT RECOMMENDED THAT THE IDE BE WITHDRAWN. FDA WITHDREW THE IDE IN APRIL 1990. OTHER REGULATORY ACTIONS ARE CURRENTLY BEING PURSUED. THIS CASE ILLUSTRATES THE AGGRESSIVE ACTION FDA TAKES AGAINST FIRMS THAT VIOLATE THE LAW AND REGULATIONS.

HEART VALVES

THE HEART VALVES WERE MADE FROM PYROLITIC CARBON, A BRITTLE MATERIAL. CRACKS OR IMPERFECTIONS IN THE MATERIAL COULD LEAD TO THE EVENTUAL FAILURE OF THE VALVES. TWO FRACTURES WERE KNOWN WHEN FDA APPROVED THE PMA APPLICATION. SUBSEQUENTLY, THE FIRM SUBMITTED 10 MORE MDRS RELATED TO VALVE FAILURES. BETWEEN 1982 AND MAY 1988

APPROXIMATELY 20,000 VALVES WERE IMPLANTED IN PATIENTS. IN EARLY 1988, FDA BECAME CONCERNED ABOUT THE FRACTURE RATE OF THE VALVES AND MET WITH COMPANY REPRESENTATIVES TO DISCUSS THE PROBLEM. THE FIRM DID NOT BELIEVE A RECALL WAS NECESSARY. EVENTUALLY, THE FIRM DECIDED TO CEASE MANUFACTURING AND DISTRIBUTING THE VALVES AND TO NOTIFY CUSTOMERS OF THE RECALL.

THIS IS A CASE WHICH ILLUSTRATES HOW FDA HAS TO PRESSURE FIRMS TO RECALL PRODUCTS. IN THIS CASE, FDA THREATENED TO WITHDRAW PREMARKET APPROVAL FOR TWO HEART VALVES IF THE MANUFACTURER DID NOT RECALL THEM.

KIDNEY LITHOTRIPTER

THE KIDNEY LITHOTRIPTER USES SHOCK WAVES TO CRUSH KIDNEY STONES INSIDE THE BODY WITHOUT SURGICAL INTERVENTION. COMPANY OFFICIALS ASSERT THAT INCORRECT USE OF THE LITHOTRIPTER CAN CAUSE SERIOUS INJURY OR EVEN DEATH. THE MOST COMMON USER ERRORS OCCUR WHEN PHYSICIANS (1) PERFORM THE PROCEDURE ON PATIENTS WITH RISKY MEDICAL OR PHYSICAL CONDITIONS OR (2) USE AN EXCESSIVE NUMBER OF SHOCK WAVES TO DESTROY THE STONES.

THE FIRM STRESSED THAT PHYSICIANS SHOULD NOT USE MORE THAN 2,000 SHOCK WAVES TO BREAK UP KIDNEY STONES. HOWEVER, WHEN THE FIRM SURVEYED USERS, AT FDA'S REQUEST, THEY FOUND THAT PHYSICIANS WERE OVERUTILIZING THIS MODE. THEREFORE, THE FIRM THEN AGREED TO RECALL

AND MODIFY THE DEVICE AND TO EDUCATE USERS ABOUT THE PROPER USE OF THE HIGH FLUOROSCOPY.

USER ERROR, AS WELL AS PROBLEMS WITH THE DESIGN OF A DEVICE, CAN LEAD TO INJURIES AND DEATH. IN THIS CASE, EVEN THOUGH THE FIRM CLAIMED THAT USER ERRORS LED TO PROBLEMS WITH THE DEVICE, FDA REQUIRED THE FIRM TO MODIFY THE DESIGN.

INSULIN INFUSION PUMP

THE INSULIN INFUSION PUMP ADMINISTERS AND REGULATES THE AMOUNT OF INSULIN ACCORDING TO THE DIABETIC'S NEEDS. IT IS WORN EXTERNALLY, AND DELIVERS THE INSULIN THROUGH A SYRINGE, THIN TUBE AND NEEDLE WHICH IS INSERTED BENEATH THE PATIENT'S SKIN. THE COMPANY DECIDED TO RECALL THE PUMP AND TWO ACCESSORIES BECAUSE OF PROBLEMS WITH LEAKAGE AT THE CONNECTION BETWEEN THE SYRINGE AND THE INFUSION SET, WHICH DELIVERS INSULIN FROM THE PUMP TO THE INFUSION POINT. FAILURE TO DELIVER THE CORRECT AMOUNTS OF INSULIN CAN LEAD TO HIGH OR LOW BLOOD SUGARS AND DIABETIC KETOACIDOSIS.

DURING A RECALL INSPECTION, THE FDA INVESTIGATOR FOUND THAT THE PROBLEMS WITH THE PUMP FAR EXCEEDED THOSE REPORTED AND TARGETED FOR CORRECTION BY THE MANUFACTURER. THE INVESTIGATOR CONCLUDED THE PUMP HAD REACHED THE MARKET DESPITE THE FACT THAT TOTALLY INADEQUATE PREMARKET TESTING HAD BEEN PERFORMED. DURING THE INSPECTION, A NUMBER OF DESIGN DEFICIENCIES AND GMP VIOLATIONS WERE

DISCOVERED INCLUDING (1)INADEQUATE SAFETY, ACCURACY, DESIGN VERIFICATION, AND RESERVOIR LEAKAGE TESTING; (2) EXTREME USER UNFRIENDLINESS; AND (3) FAILURE TO PROPERLY ASSESS COMPLAINTS, ANALYZE FAILURES, AND COMPLY WITH THE MDR REGULATION. ALTHOUGH THE MANUFACTURER HAD RECEIVED 1,500 REPORTABLE COMPLAINTS, IT HAD ONLY FILED 15 MDRS BEFORE THE RECALL.

IN THIS CASE BECAUSE GMP INSPECTIONS CONCENTRATED ON THE MANUFACTURER'S MAJOR PRODUCTS AND THE MANUFACTURER DID NOT COMPLY WITH THE MDR REGULATION, FDA WAS UNAWARE OF THE SEVERITY OF PROBLEMS WITH THE INSULIN PUMP UNTIL THE DISTRICT OFFICE CONDUCTED THE RECALL INSPECTION.

MICROPROCESSOR VENTILATOR

THE MICROPROCESSOR VENTILATOR PROVIDES GASES TO PATIENTS WHO REQUIRE RESPIRATORY ASSISTANCE. TWO TYPES OF FAILURES WERE INVOLVED. FIRST, THE WATCHDOG TIMER CIRCUIT, WHICH ANALYZES THE FUNCTIONING OF THE MICROPROCESSOR FAILED. THIS CAUSED THE DEVICE TO CEASE VENTILATING WITHOUT AUDIBLE OR VISUAL ALARM. SECOND, THE DEVICE WOULD CEASE VENTILATING IF ITS NEBULIZER WERE DISCONNECTED PRIOR TO AN OPERATOR MANUALLY SETTING A VENTILATING TIME CYCLE.

AFTER INVESTIGATING SEVERAL COMPLAINTS, TWO INVOLVING DEATHS, THE FIRM RECALLED THE DEVICE. IT INTENDED TO CORRECT EACH UNIT BY INSTALLING NEW SOFTWARE. INITIALLY THE DISTRICT OFFICE FOUND THE

RECALL TO BE INEFFECTIVE AND THE FIRM DECIDED TO RECONTACT ALL OF ITS CUSTOMERS.

ALTHOUGH THE DISTRICT OFFICE EVENTUALLY CONCLUDED THAT THIS RECALL WAS EFFECTIVE, THEY SUBMITTED AN INJUNCTION RECOMMENDATION TO FDA. THEY BELIEVED THAT REPEATED GMP VIOLATIONS BY THE FIRM IMPAIRED THE FIRM'S ABILITY TO PRODUCE A SAFE PRODUCT, PARTICULARLY THE VENTILATOR. THE FDA DISAPPROVED THE RECOMMENDATION FOR INJUNCTION, STATING THAT THE FIRM'S PROPOSED CORRECTIVE ACTIONS WOULD ADDRESS THE GMP DEVIATIONS. ALTERNATIVELY, IT SUGGESTED THAT THE DISTRICT ISSUE A NOTICE OF ADVERSE FINDINGS.

HEMOPERFUSION DEVICES

HEMOPERFUSION DEVICES ARE PRODUCTS USED TO CLEANSE THE BLOOD OF FOREIGN MATTER, SUCH AS METALS AND DRUGS. AN INSPECTION OF THIS FIRM REVELED SEVERAL AREAS OF CONCERN TO THE FIELD INVESTIGATOR. THE INVESTIGATOR FOUND (1) 48 REPORTS FILED BY HEALTH PRACTITIONERS, ONLY ONE OF WHICH HAD BEEN REPORTED TO THE FDA THROUGH THE MDR SYSTEM AND (2) THE FIRM HAD NOT ADEQUATELY REVIEWED THE REASONS FOR THE DEVICE-RELATED PROBLEMS, SUCH AS BLOOD CLOTTING, BLOOD SEPARATION, AND ETHER ODOR EMITTED FROM PATIENTS. ACCORDING TO THE INSPECTOR, 28 OF THE 47 UNREPORTED COMPLAINTS APPEARED TO INVOLVE MALFUNCTIONS AND/OR SERIOUS INJURY. THEREFORE, THESE SHOULD HAVE BEEN REPORTED TO FDA. THE OTHER 19 COMPLAINTS INDICATED DESIGN PROBLEMS AND MAY HAVE REQUIRED REPORTING TO FDA.

THIS INSPECTION REPORT WAS REFERRED TO FDA FOR ASSESSMENT AND REGULATORY FOLLOW-UP DECISION, SUCH AS ISSUING A NOTICE OF ADVERSE FINDINGS. ALTHOUGH THIS INSPECTION REPORT WAS FORWARDED IN 1987, FDA'S RECORDS INDICATE THAT NO SUCH FOLLOW-UP OCCURRED.

IN THIS CASE WE SEE HOW SOME ACTIONS CAN GET LOST OR BURIED IN THE PAPER WORK. THIS CASE ILLUSTRATES THE NEED FOR A SYSTEM TO ASSURE THAT INSPECTION RESULTS ARE PROPERLY FOLLOWED-UP.

PLASMAPHERESIS EQUIPMENT

PLASMAPHERESIS EQUIPMENT IS USED AT PLASMAPHERESIS CENTERS IN THE COLLECTION OF BLOOD PRODUCTS FROM DONORS. ALLEGATIONS MADE BY AN FDA INSPECTOR, ON HIS OWN INITIATIVE, INVOLVED DEFECTIVE PLASMAPHERESIS EQUIPMENT INCLUDING Y-TYPE ADMINISTRATION SETS AND PLASMA POOLING BOTTLES. THE Y-TYPE ADMINISTRATION SETS ARE USED IN CONJUNCTION WITH BLOOD COLLECTION BAGS DURING THE PLASMA EXTRACTION PROCESS. BLOOD COLLECTION BAGS WERE FREQUENTLY PUNCTURED BY THE EXTENDED AND POINTED Y-SET SPIKES CAUSING CONTAMINATION OF THE BLOOD PRODUCT. IN ADDITION, MEDICAL STAFF WERE OFTEN LACERATED BY THE EXTENDED SPIKES OF THE Y-SETS ALLOWING EXPOSURE TO UNTESTED BLOOD. PROBLEMS ASSOCIATED WITH THE PLASMA POOLING BOTTLES INCLUDED LEAKAGE AND POSSIBLE TIPPING OVER DURING THE FILLING PROCESS. BOTH PROBLEMS EXPOSED TECHNICIANS AND OTHERS TO CONTAMINATION FROM UNTESTED PLASMA.

IN THIS CASE, ALTHOUGH THE MANUFACTURER'S MODIFICATIONS TO THE Y-SETS CORRECTED THE DEFECTS, THEY WERE NOT REPORTED TO FDA. ALSO, FDA DID NOT LEARN OF THE MODIFICATIONS UNTIL AFTER AN INSPECTION OF THE MANUFACTURER'S FACILITY WAS CONDUCTED, NEARLY 6 MONTHS AFTER THE COMPLAINT WAS RECEIVED.

AS TO THE PLASMA POOLING BOTTLES, THE FDA HEALTH HAZARD EVALUATION COMMITTEE REJECTED A RECOMMENDATION MADE BY THE DISTRICT OFFICE THAT THE BOTTLES BE SEIZED. INSTEAD, THE COMMITTEE DETERMINED THAT THIS PRODUCT DID NOT PRESENT A DANGER TO HEALTH, BUT THAT ADDITIONAL PRECAUTIONARY STATEMENTS WERE NEEDED TO SUPPLEMENT THE DIRECTIONS FOR USE.

THIS CASE ILLUSTRATES HOW LONG IT TAKES FDA TO ACT SOMETIMES. IT TOOK FDA MORE THAN 9 MONTHS TO REACH THIS DECISION FROM THE TIME THE PROBLEM WAS FIRST REPORTED AND 7 MORE MONTHS TO NOTIFY THE MANUFACTURER TO REVISE THE BOTTLE LABELS.

MEDICAL DEVICE INVESTIGATIONS

BEFORE 1989, THE NUMBER OF FDA-RELATED CRIMINAL INVESTIGATIONS CONDUCTED BY THE OIG WERE MINIMAL, USUALLY INVOLVING FDA EMPLOYEES AND OTHER INTERNAL MATTERS. CIRCUMSTANCES, MOST NOTABLY THE GENERIC DRUG SCANDAL, CAUSED INCREASED INVOLVEMENT IN FDA-RELATED MATTERS. OUR INVESTIGATIONS INCREASED FROM 12 CASES IN 1988 TO OVER 200 CASES IN 1990. OUR MAIN FOCUS HAS BEEN ON DRUGS AND

BIOLOGICS, BECAUSE OF THE GENERIC DRUG SCANDAL AND NEW LEGISLATION IN THE PRESCRIPTION DRUG AND ANABOLIC STEROID AREA. NEVERTHELESS, WE DID UNDERTAKE SEVERAL INVESTIGATIONS IN WHICH UNSCRUPULOUS MEDICAL DEVICE MANUFACTURERS APPEARED TO BE DEFRAUDING THE FDA AND EXPOSING THE AMERICAN PUBLIC TO DANGER.

FOR EXAMPLE, IN ONE CASE A DIAGNOSTIC LABORATORY ALLEGEDLY USED TAINTED BLOOD IN THEIR PRODUCTION OF MEDICAL DIAGNOSTIC DEVICES. IT WAS ALSO ALLEGED THAT THEY ALTERED PRODUCTION RECORDS IN ORDER TO CONCEAL FROM THE FDA THE FACT THAT THEY USED THE TAINTED BLOOD IN THE DIAGNOSTIC TESTING DEVICE.

IN ANOTHER CASE, THE MANUFACTURER OF A KIDNEY DIALYSIS MACHINE ALLEGEDLY USED SUBSTANDARD METAL FASTENERS AND PROVIDED FALSE STATEMENTS TO THE FDA IN REPORTS TO THEM, A FELONY VIOLATION OF THE ACT AND OTHER FEDERAL CRIMINAL LAWS.

FURTHER, A MEDIAL DEVICE COMPANY ALLEGEDLY FAILED TO FILE REPORTS THAT ITS APNEA MONITOR, A DEVICE USED ON INFANTS PRONE TO SUDDEN INFANT DEATH SYNDROME, WAS INVOLVED IN SITUATIONS IN WHICH DEATH OR SERIOUS INJURY OCCURRED IN AT LEAST 80 CASES.

THESE AND MANY OTHER INVESTIGATIONS WERE BEING CONDUCTED UNDER AUTHORITY DELEGATED TO THE INSPECTOR GENERAL BY THE SECRETARY OF HHS. THE SECRETARY RESCINDED THIS DELEGATION EFFECTIVE JANUARY 29, 1990. AT THAT TIME, THE OIG WITHDREW FROM THESE CASES.

CONCLUSION

OUR REPORTS LIST A NUMBER OF RECOMMENDATIONS WHICH ADDRESS THE PROBLEMS IN THE 510(K) PROCESS AND THE POSTMARKET SURVEILLANCE ACTIVITIES. FOR EXAMPLE, WE RECOMMEND THAT THE FDA AUGMENT THE PREMARKET NOTIFICATION PROCESS BY DESIGNING A PROGRAM FOR SELECTIVELY TESTING DEVICES, VALIDATING TEST RESULTS SUBMITTED IN 510(K)S, AND CONDUCTING PREMARKET INSPECTIONS OF MANUFACTURERS' FACILITIES. ADDITIONALLY, WE RECOMMEND THAT THE FDA CLARIFY THE MDR REGULATION AND SEEK LEGISLATIVE AUTHORITY TO REQUIRE MANDATORY NOTIFICATION OF VOLUNTARY RECALLS AND TO PROMPTLY INITIATE RECALLS.

THIS CONCLUDES MY TESTIMONY. I WOULD BE HAPPY TO ANSWER ANY QUESTIONS YOU MIGHT HAVE.

Mr. WAXMAN. I will call on Mr. Wisler.

STATEMENT OF CARL E. WISLER

Mr. WISLER. It is a pleasure for me to be here today to discuss some of the work the General Accounting Office has done in the area of medical devices. As you noted, I am accompanied by Dr. Dillingham. Also as you have noted, I submitted my full testimony for the record, and I will briefly summarize the main points.

During the last 4 years, we have issued eight reports in this area and have presented testimony before this subcommittee on two previous occasions. These reports and testimonies have focused on the Food and Drug Administration's premarket review processes for devices and device recalls, and FDA's implementation of, the medical device reporting regulations.

In February 1989, we reported evidence that some medical device manufacturers may have been overreporting problems with devices, while others either were not reporting at all or were underreporting.

Since the release of our report, we have received additional information from several sources suggesting that problems are underreported and that underreporting is not always identified through FDA's inspection program.

On September 18, 1989, you asked us to investigate a citizen's report to GAO of numerous unreported deaths of patients associated with the Aequitron Medical, Inc. Model 8200 home apnea monitor.

Apnea is a prolonged lack of respiration that can result in low blood oxygen levels, which can lead in turn to brain damage and death.

Apnea monitors are electronic devices intended to detect episodes of apnea. In a typical device, when either breathing or heart rate falls before set levels or when the device's electrical leads are improperly attached to a patient, both audible alarms and flashing lights are triggered.

Specialized models of apnea monitors are designed for hospital and home use. To avoid lengthy hospital stays, home apnea monitors have been increasingly used in recent years. Most of the patients are infants.

We undertook a case study of the Aequitron model home apnea monitor and asked these questions:

How many complaints involving the death of patients have been associated with Aequitron's Model 8200 home apnea monitor? Did the device manufacturer comply with FDA's existing problem-reporting requirements and procedures? What actions did FDA take when it received information from the device manufacturer or other sources that model 8200 had been associated with numerous deaths?

In this testimony, I will concentrate on the findings, conclusions and recommendations of this case study.

I should note, our methodology precludes generalizing from these findings and conclusions to other devices and manufacturers. Instead, the study's function is to illustrate some of the critical con-

cerns that we identified in our earlier generalized work on the implementation of the medical device reporting regulations.

Included there were concerns about the overall efficacy of the FDA medical device reporting regulation compliance program and, in particular, the finding that a number of FDA inspections had discovered instances in which reportable serious injuries and deaths had been recorded in a manufacturer's files but not reported to the Agency.

Let me summarize the answers to the three questions. The first question: How many complaints involving the death of patients have been associated with Aequitron Model 8200 home apnea monitor? The model 8200 was introduced into the market in June 1982. The manufacturer reports that some 30,000 monitors were distributed between 1982 and 1987, but it is not possible to estimate the actual number in use, or the frequency of their use.

Model 8200 was discontinued in 1987 and replaced by model 9200. The answer to the question is, between January 1983 and January 1989, Aequitron received at least 70 complaints that the deaths of patients were associated with the use of their apnea monitor.

Aequitron also received an additional 80 complaints about the monitor, of which 14 claimed injuries or safety hazards, but not deaths. Two points should be noted about the 70 complaints associated with deaths.

First, the manufacturer says some of the complaints do not allege a malfunction of the motor. And, second, we did not independently investigate whether the reported events actually occurred, nor whether the reported deaths were caused by the apnea monitor. Such investigations are the responsibility of the manufacturer and of the Food and Drug Administration.

Let me now turn to the second question that we posed. Did the device manufacturer comply with FDA's problem-reporting regulations and procedures? We found Aequitron had maintained the required record of complaints, but had not fully complied with the requirements of reporting the problems to FDA.

In cases of death or serious injury, the medical device reporting regulation, effective 1984, required device manufacturers telephone an initial report to the FDA within 5 calendar days, and a more complete written report must follow within 15 working days.

For other kinds of cases that must be reported, but do not involve death or serious injury, the deadline is 15 working days. Manufacturers must make a judgment, although they are not required to report every complaint associated with death or injury, they are required to report a case if they become aware of information that reasonably suggests one of their devices may have caused or contributed to serious injury or death or has malfunctioned in such a way if the malfunction were to reoccur, the device would be likely to cause or contribute to serious injury or death.

In Aequitron's case, 56 of the 70 accounts of death came after the 1984 reporting regulation went into effect. So, 56 cases were at least candidates for reporting to FDA. More than 56 cases were candidates on the grounds that some involved serious injury, a safety hazard, or were of a type of malfunction which at some time might be associated with death or serious injury.

When we looked at FDA records, we found at least 51 of the 56 complaints of Aequitron associated with death had not been reported to the Food and Drug Administration. FDA has reviewed some of those unreported complaints, and has concluded at least six of the unreported cases should have been reported.

Thus, from our analysis, we conclude that Aequitron did not fully comply with medical device reporting regulations, but the extent of underreporting is not yet known.

This leads to the third question: What actions did FDA take when it received information from the device manufacturer or other sources that model 8200 has been associated with numerous deaths?

The short answer, after the FDA received information about the association of the Aequitron monitor with deaths, the Agency decided, for maybe several reasons, to investigate whether more of the complaints received by the manufacturer should have been reported.

Following the investigation, FDA cited Aequitron for noncompliance for the reporting regulation, and in concert with the manufacturer, reviewed the manufacturer's problem-reporting policy. FDA reviewed a revised policy submitted by Aequitron and concluded it appeared adequate. These actions resulted in submission of more than 150 additional reports to FDA.

Now, let me elaborate a little bit on what happened. Between August 1984 and June 1989, FDA had various contacts with Aequitron, including at least eight formal inspections. Three of these were the so-called inspections for good manufacturing practice, and two of these looked specifically at how Aequitron handled medical device reporting requirements.

Five of the inspections were those known as for-cause inspections including three initiated in response to complaints FDA had received.

In May 1988, FDA inspectors identified cases in Aequitron's files they believe should have been reported. As a result of this inspection, FDA issued a notice of adverse findings letter to Aequitron, indicating noncompliance with medical device reporting regulations.

Representatives of the manufacturer stated FDA's finding stemmed from a difference of interpretation of the regulations. After discussion of the issues with Aequitron, FDA concluded in 1989 that six of the cases should have been reported.

We have, however, questioned FDA's basis for reducing the number of reportable cases, and FDA now agrees with our analysis.

Let me now finish with the conclusions from our study, and as it fits into our overall broader piece of work.

Mr. WAXMAN. If you could go through that very quickly, because we have run out of time allotted to your testimony. Of course, that will all be in the record.

Mr. WISLER. Let me make one final statement, then. Our study illustrates the serious consequences, the shortcomings implementation of the medical devices reporting regulation and subsequent inspection can have.

In the case of the home apnea monitor, FDA did not have the information on a number of adverse experiences with the device,

and the Agency made decisions with respect to recalls and other regulatory actions. FDA found Aequitron's interpretation of the reporting requirements differed from the Agency's in ways that put it in noncompliance with the regulation.

That concludes my statement, Mr. Chairman. I will be happy to respond to questions from you.

[Testimony resumes on p. 132.]

[The prepared statement of Mr. Wisler follows:]

STATEMENT OF CARL E. WISLER

Mr. Chairman and Members of the Subcommittee:

It is a pleasure to be here today to discuss some of the work that the General Accounting Office (GAO) has done in the area of medical devices. During the last 4 years, we have issued eight reports in this area and have presented testimony before this Subcommittee on two previous occasions. These reports and testimonies have focused on the Food and Drug Administration's (FDA's) premarketing review processes for devices and device recalls and FDA's implementation of the medical device reporting regulation.

Medical devices include almost everything, other than drugs, that health-care professionals use to diagnose, treat, or prevent illness, improve human functioning, and support and sustain life.[1] More than 1,700 different types of medical devices are available in

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[1]Section 201(h) of the Federal Food, Drug, and Cosmetic Act of 1938, as amended by the Medical Device Amendments of 1976, defines "device" as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is (1) recognized in the official National Formulary or the U.S. Pharmacopeia or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals, or (3) intended to affect the structure or any function of the human body or bodies of other animals and that does not achieve any of its principal intended purposes through chemical action within or on the body and does not depend upon being metabolized in order to achieve any of its principal intended purposes. The effect of the amendments was to enlarge the 1938 definition of "device" to include (1) devices intended for use in the diagnosis of conditions other than disease, such as pregnancy, (2) in vitro diagnostic products, and (3) specific products previously regulated as new drugs, including soft contact lenses, bone cement, and sutures.

the United States today. They represent an industry of more than $17 billion a year. FDA is authorized to regulate medical devices during all phases of their development, testing, production, distribution, and use.

In February 1989, we reported to this Subcommittee that our review of the implementation of the medical device reporting regulation had found evidence that some medical device manufacturers may have been overreporting problems with devices, while others either were not reporting at all or were underreporting.[2] In its comments on the report, FDA said that our conclusion that the industry was underreporting was "questionable" and that FDA's medical device reporting regulation compliance inspection strategy was sufficient to identify compliance problems. Since the release of our report, we have received additional information from several sources suggesting that problems are underreported and that underreporting is not always identified through FDA's inspection program.[3]

On September 18, 1989, you asked us to investigate a citizen's report to GAO of numerous unreported deaths of patients

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[2]See U.S. General Accounting Office, Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation, GAO/PEMD-89-10 (Washington, D.C.: February 1989), p. 3.

[3]The sources include citizen reports, device industry publications, consultation with members of our expert review panel, and review of individual recalls in connection with our report entitled Medical Device Recalls: Examination of Selected Cases, GAO/PEMD-90-6 (Washington, D.C.: October 1989).

associated with the Aequitron Medical, Inc., Model 8200 home apnea monitor and to include our investigation in our ongoing review of FDA's postmarketing surveillance of medical devices for the Subcommittee.

FDA has identified the apnea monitor as a "critical device." Critical devices are intended for surgical implant into the body or to support or sustain life. Their failure to perform when used properly in accordance with instructions provided in the labeling may sometimes be reasonably expected to result in a significant injury to the user.

Apnea is a prolonged lack of respiration that can result in low blood oxygen levels, which can lead in turn to brain damage and death. The condition can be induced by a variety of underlying medical disorders. However, premature and low birthweight infants are particularly prone to apnea.

Apnea monitors are electronic devices intended to detect episodes of apnea. In a typical device, when either breathing or heart rate falls below set levels or when the device's electrical leads are improperly attached to a patient, both audible alarms and flashing lights are triggered. Specialized models of apnea monitors are designed for hospital and home use. To avoid lengthy hospital stays, home apnea monitors have been increasingly used in recent years.

With the concurrence of the Subcommittee staff, we undertook a case study based on three specific questions:

-- How many complaints involving the death of patients have been associated with Aequitron's Model 8200 home apnea monitor?

-- Did the device manufacturer comply with FDA's existing problem-reporting regulations and procedures?

-- What actions did FDA take when it received information from the device manufacturer or other sources that Model 8200 had been associated with numerous deaths?

In this testimony, I will concentrate on the findings, conclusions, and recommendations of this case study.[4]

Our case study methodology precludes generalizing from these findings and conclusions to other devices and manufacturers. Instead, the study's function is to illustrate some of the critical concerns that we identified in our earlier generalized work on the implementation of the medical device reporting regulation. Included there were concerns about the overall efficacy of the FDA medical device reporting regulation compliance

[4]See U.S. General Accounting Office, Medical Devices: Underreporting of Serious Problems With a Home Apnea Monitor, GAO/PEMD-90-17 (Washington, D.C.: May 1990).

program and, in particular, the finding that a number of FDA inspections had discovered instances in which reportable serious injuries and deaths had been recorded in a manufacturer's files but not reported to the agency. The data on which this study is based were collected between September 1989 and December 1989.

I will begin with an overview of our findings and conclusions. Then, I will discuss our findings with regard to each of the evaluation questions in greater detail.

OVERVIEW

First, we found that between January 1983 and January 1989, Aequitron had received at least 70 complaints that the deaths of patients were associated with the use of the Model 8200 home apnea monitor.[5]

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[5]We found that an Aequitron document entitled "H/I/Death File" (or "Hazard, Injury, Death (HID) File") contained information abstracted from the special section of the record of complaints reserved for hazards to safety, injuries, and deaths that a device manufacturer is required to maintain under the good manufacturing practices (GMP) regulation (21 C.F.R. 820.198). The HID file listed 82 complaints, 68 of which referred to deaths. Two additional complaints of death were contained in a similar list drawn from the "general" portion of Aequitron's GMP record of complaints. According to the manufacturer, the HID file contains complaints alleging that serious injuries or deaths were associated with the device, but some of the complaints do not allege that a malfunction of the monitor occurred. We did not independently investigate each complaint on the list to determine the circumstances of the events; causal connections between the device and the safety hazard, injury, or death; or the actual occurrence of the events listed.

Second, we found that the manufacturer had maintained the required record of complaints but had not fully complied with the reporting requirements of the medical device reporting regulation.[6] A partial review of the manufacturer's complaint record by FDA found that 10 unreported complaints should have been reported, including 4 that involved the death of patients. We could verify that only 6 of the complaints of deaths dated after the implementation of the medical device reporting regulation were reported to FDA. Two of these complaints of death were reported only after FDA compliance actions, nearly 1 year after the events.

And, third, we found that when FDA received information about the association of the monitor with deaths, it investigated whether a sample of complaints should have been reported to FDA. Following the investigation, FDA cited the device manufacturer for noncompliance with the medical device reporting regulation and, in concert with the manufacturer, reviewed the manufacturer's problem-reporting policy. FDA then reviewed a revised problem-reporting policy submitted by the manufacturer and concluded that it

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[6]The medical device reporting regulation, effective December 13, 1984, requires that device manufacturers report to FDA whenever they become aware of information that reasonably suggests that one of their devices may have caused or contributed to a serious injury or death or has malfunctioned in such a way that, if the malfunction were to recur, the device would be likely to cause or contribute to serious injury or death. See Medical Devices: FDA's Implementation for a detailed discussion of the medical device reporting regulation.

"appeared adequate." These actions resulted in the submission of more than 150 additional reports to FDA.

In sum, our findings with regard to this study of an apnea monitor are consistent with our earlier finding of differences in the interpretation of medical device reporting requirements.[7] In this case, a manufacturer's interpretation of the requirements has resulted in the underreporting of serious problems associated with its device. It also illustrates a weakness in the compliance inspection process. Although the manufacturer had been the subject of several inspections, it was nearly 4 years after the medical device reporting regulation went into effect before FDA's inspection program identified and attempted to resolve the underreporting.

In the course of our study, we also learned that the parents and other laypersons who are the primary users of home apnea monitors are not always adequately informed about the limitations and risks of these devices. The current technology is, for example, unable to detect some kinds of apnea, and some monitors may be overly sensitive to interference from electronic appliances found in the home or the motion of other objects near them--for example, parents' bodies or fluttering window curtains. The instructions and training that accompany such devices may not make such limitations sufficiently clear to permit parents to make well-

[7] Medical Devices: FDA's Implementation, p. 4.

informed decisions about the risks of using the devices or about using them in ways that minimize the risks.

Let me now turn to a more detailed discussion of our findings with regard to our three specific evaluation questions.

Question 1: Complaints of Death

Our first evaluation question was: How many complaints of the deaths of patients were associated with the Aequitron Medical, Inc., Model 8200 home apnea monitor?

We received information through the GAO hotline that there was evidence of serious nonreporting or underreporting of problems associated with Model 8200.[8] We were also told that many of the unreported complaints involved the deaths of the patients.

FDA's "good manufacturing practices" regulation requires that manufacturers maintain two types of records regarding the complaints they receive from users about their products.[9] The first is a general record of users' complaints. The second is a record exclusively devoted to complaints alleging that hazards to

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[8]This information was simultaneously provided to the staff of the Subcommittee.

[9]Section 520(f) of the 1938 Federal Food, Drug, and Cosmetic Act, added by the Medical Device Amendments of 1976, authorizes FDA to promulgate regulations that specify practices in the manufacture, packaging, storage, and installation of devices. The good manufacturing practices established by the regulation include controls over manufacturing, specifications, processing procedures, device components, packaging, labeling, manufacturing equipment, and records.

safety, injuries, or deaths are associated with a medical device.

Evidence subsequently provided to us included a table labeled "H/I/Death File" and identified users' complaints related to the Aequitron Medical, Inc., Model 8200 home apnea monitor. The table contained 82 complaints with four categories of information for each complaint.[10]

We investigated the origin and contents of the HID file and we determined that it was in fact a list of complaints derived from the device manufacturer's "hazard, injury, or death" record. This is the record required by the GMP regulation. The list contained complaints that the device manufacturer had received about its Model 8200 apnea monitor dated between January 1983 and January 1989.[11]

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[10]See footnote 5 above. The four data categories for each complaint were serial number, date of complaint, reason for return, and analysis. For 71 out of 82 complaints listed on the HID file, the "analysis" category listed the device as "in-spec" or "fully functional." It is important to note with regard to the analysis category that the general limitations of the technology employed in apnea monitors or the specific limitations of the design of a particular model may cause a monitor to fail to detect apnea events in some circumstances. Such an occurrence is known as a "false negative." If this happens, later testing of the monitor would not necessarily reveal that a component had malfunctioned, and the device could be found to be "within specifications" or "fully functional."

[11]Model 8200 was introduced into the market in June 1982. According to the manufacturer, approximately 30,000 of the monitors were distributed between 1982 and 1987, but it is not possible to estimate the number in actual use or their frequency of use.

Our analysis of the HID file showed that it listed 68 complaints in which the word "death" was included in the category of reasons for the device's return to the manufacturer. Further research found that a similar list drawn from the manufacturer's general complaint record contained 2 additional complaints in which the word "death" was included. There were therefore a total of 70 complaints in which the allegation of a patient's death was included in the complaint description.[12] The remaining 14 complaints in the HID file were complaints that included allegations of either hazards to safety or injuries. (See table 1. The remainder of the table is discussed below.)

Table 1: Complaints and Medical Device Reporting Regulation Reports on Aequitron Medical, Inc., Model 6200 Apnea Monitor

	Complaints in Aequitron's files			Medical device reporting regulation reports to FDA		
	In "H/I/Death File"	In "general" file	Total	Before FDA's May 1988 inspection	After FDA's May 1988 inspection	Total
Deaths	68	2	70	5	2	7
Nondeaths	14	66	80	78	193	271
Total	82	68	150	83	195[a]	278

[a]150 of these reports were submitted in response to FDA compliance actions

Question 2: Compliance

Our second evaluation question was: Did the device manufacturer comply with FDA's existing problem-reporting regulations and procedures?

[12]The manufacturer confirmed that these were complaints alleging that a death had been associated with the use of the device.

FDA's primary source of information about problems associated with the use of medical devices consists of the manufacturer's reports generated by the requirements of the medical device reporting regulation (21 C.F.R. 803). This regulation requires that device manufacturers telephone an initial report to FDA on serious injuries and deaths within 5 calendar days, and it requires that this be followed by a more complete written report within 15 working days. Reportable malfunctions that do not involve serious injury or death must be reported within 15 working days of the manufacturer's receiving the device-problem information. One important source of information that leads to medical device problem reports is complaints to the manufacturer, which can be made by health-care professionals or other users of devices.[13]

We compared the 70 complaints that contained the word "death" with FDA's record of medical device problem reports and found that 14 complaints were dated before the medical device reporting regulation was promulgated. The significance of this is that before the regulation was promulgated, the device manufacturers' obligations were fulfilled by maintaining general complaint records and making them available to FDA during GMP inspections. However, we found 56 complaints associated with deaths whose listed dates fell after the medical device reporting regulation was implemented.

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[13]According to the GMP regulation, a complaint is a written or oral expression of dissatisfaction regarding the identity, quality, durability, reliability, safety, effectiveness, or performance of a device.

Only 4 reports in FDA's medical device reporting data base as of September 1989 could be confirmed as corresponding to complaints from the list of 56 and, therefore, as having been reported to FDA in accordance with the provisions of the regulation. One additional medical device problem report on a death associated with Model 8200 was reported to FDA during this time but could not be identified with a specific complaint on the HID file, because the manufacturer had not submitted a serial number with the medical device problem report. Thus, at least 51 of the 56 complaints of death had not been reported before FDA began to take compliance actions.

The information in the HID file alone was not sufficient for us to make a definitive judgment about the reportability of the complaints or to establish causal connections between the device and the safety hazard, injury, or death. The examination of the manufacturer's complete record for each complaint, which would be necessary for such assessment, was beyond the scope of our review. In a partial review of the complaint record, FDA found that 10 unreported complaints should have been reported, including 4 that alleged the death of patients.[14]

It is important to note that not all incidents in which a device is associated with the death of a patient must necessarily

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[14]A more detailed discussion of this review is contained in the following section of this report on FDA's actions.

be reported to FDA under the medical device reporting regulation. The regulation requires reporting incidents to FDA only if the information in the possession of the manufacturer "reasonably suggests" that a device may have caused or contributed to a death or a serious injury. If a health-care professional states to the manufacturer that this has happened, then the manufacturer is required to file a medical device problem report.[15] But in the case of a report from a layperson, if an immediate investigation by the manufacturer reveals that a patient was not connected to an apnea monitor at the time of death, or that the monitor's alarm sounded and the caregiver was alerted even though the patient could not be revived, then a report might not be required. FDA has characterized the circumstances in which home apnea monitors are used and the limitations of the technology they employ as sometimes making it difficult to determine whether a problem is reportable under the medical device reporting regulation.

Question 3: FDA's Actions

The third question our study addressed was: What actions did FDA take when it received information from the device manufacturer

[15]According to the "per se" reporting rule, whenever a health care professional advises a manufacturer that one of its devices may have caused or contributed to a serious injury or death, the manufacturer is "per se" in receipt of information that "reasonably suggests" that a device may have caused or contributed to a serious injury or death and must therefore report the event. It does not, however, imply that similar reports from persons other than health-care professionals are not reportable.

or other sources that Model 8200 had been associated with numerous deaths?

One of the principal tools of FDA's postmarketing surveillance of medical devices is biennial inspections for compliance with the GMP regulation. In addition, FDA conducts "for cause" inspections when they are warranted by complaints or other evidence of problems with devices.[16] FDA assesses device manufacturers' compliance with the medical device reporting regulation by executing a special medical device reporting inspection program as part of its GMP inspections. The results of these inspections can lead to additional actions by the agency.[17]

We found that between August 1984 and June 1989, FDA had various contacts with Aequitron, including at least eight formal inspections. Three were GMP inspections, and two of these included the medical device reporting component. Five were "for cause," including three that were initiated in response to complaints FDA had received. One was a follow-up to a medical device problem report on Model 8200, and one was a follow-up to an

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[16]A principal rationale for "for cause" inspections is information developed by FDA analysts who monitor and compare reports submitted through FDA's voluntary problem-reporting program, device recalls, and the medical device reporting system.

[17]According to FDA, the inspection strategy adopted by the agency will result in a medical device reporting regulation compliance inspection for every firm manufacturing medium-risk (class II) and high-risk (class III) devices at least once every 4 years and incorporating manufacturers of low-risk (class I) devices less frequently.

FDA district office's recommendation to recall Model 8200.

During a May 1988 GMP inspection, FDA examined the manufacturer's complaint records and identified 10 unreported complaints that FDA inspectors believed met the medical device reporting regulation's definitions of reportable events. Four of these complaints contained allegations of the death of patients. As a result of this May 1988 inspection, a notice-of-adverse-findings letter indicating "noncompliance" with the medical device reporting regulation was issued to the manufacturer in October 1988.[18]

Representatives of the manufacturer stated that FDA's finding of "noncompliance" resulted from a difference in the interpretation of the medical device reporting requirements. According to the manufacturer, many of the unreported complaints had not been made by health-care professionals and could not be confirmed by the company within the required reporting time. Therefore, in accordance with its interpretation of the "per se" provision of the medical device reporting regulation and company policy, Aequitron did not submit these types of reports.

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[18]A notice-of-adverse-findings letter may be sent to a manufacturer when an inspection reveals that a manufacturer or individual is in violation of the laws and regulations or when there is information that an existing condition or practice may lead to a violation if left uncorrected (although the agency has concluded that the nature of the violation does not require immediate action against the manufacturer or individual).

In our earlier study of the implementation of the medical device reporting regulation, we reported that the evidence suggested an undetermined amount of overreporting by some device manufacturers and that others were either not reporting or underreporting.[19] The most frequently identified dimension of noncompliance noted by FDA inspectors was failure to establish adequate procedures for handling complaints to determine their reportability (20 percent of all such citations for the first series of medical device reporting regulation compliance inspections and 53 percent for the second series).[20] We also encountered variations in the interpretation of reporting requirements among the FDA officials and staff we interviewed.

As a result of the October 1988 notice-of-adverse-findings letter and negotiations between FDA officials and the apnea monitor manufacturer, the manufacturer agreed to review its complaint records and revise its medical device reporting policy. Subsequently, Aequitron submitted medical device problem reports on 6 of the 10 incidents listed in the notice-of-adverse-findings letter, including 2 of the complaints in the HID file involving deaths. These 2 reports of death were submitted 1 year and 9 months, respectively, after the events they described.[21] The

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[19]See Medical Devices: FDA's Implementation, p. 61.

[20]See Medical Devices: FDA's Implementation, p. 59.

[21]The manufacturer and FDA subsequently agreed that 4 of the 10 complaints cited in the notice-of-adverse-findings letter were not reportable incidents.

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manufacturer also submitted 144 reports of malfunctions involving confirmed alarm failures.[22] Aequitron thus submitted at least 150 medical device problem reports in response to FDA compliance actions. (See table 1.)

After we had completed the data collection for our report, FDA conducted a comprehensive good manufacturing practices and medical device reporting regulation inspection of Aequitron. FDA indicated when it reviewed our draft report that it was reviewing the results of this inspection to determine what regulatory action was warranted.

Aequitron also submitted a revised medical device reporting policy to FDA, and FDA notified the manufacturer that its revised policy was adequate. However, we found certain aspects of the revised reporting policy to be inconsistent with the medical device reporting regulation. Specifically, we believe that it is improper to condition the reporting requirement on either the confirmation or the observation of a malfunction.[23] The Department of Health and Human Service (HHS) agreed with this opinion. The agency acknowledged that the Center for Devices and

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[22]Apnea monitor alarms meet FDA's definition of a "critical device component"--that is, any component of a critical device whose failure to perform can be reasonably expected to cause the failure of a critical device or to affect its safety or effectiveness.

[23]Medical device problem reports of malfunctions were submitted. Malfunction reports describe problems whose occurrence was not associated with the injury or death of a patient but that may result in injury or even death if they should recur.

Radiological Health (CDRH) made an error in allowing Aequitron to make its reporting of complaints contingent on the confirmation or observation of a malfunction. HHS stated that the firm was notified of the correct interpretation at the time of the inspection we referred to earlier.

The time required in this case for FDA to identify the underreporting problem raises questions about the effectiveness of the agency's inspection program and its capacity to identify potentially serious device problems through monitoring complaints. The inspection strategy is designed to include special emphasis on firms manufacturing the types of device that have demonstrated reportable problems and scheduling more frequent medical device reporting regulation inspections for those manufacturers.

A number of inspections took place after complaints of alarm failure had been received by the manufacturer. Nine of the complaints in the HID file involving alarm problems and the death of patients are dated before the manufacturer underwent its first GMP inspection. By the end of the manufacturer's third year of operations and before a second FDA inspection, it had received an additional seven complaints of alarm problems and deaths. According to the device manufacturer, all the complaints that had been received with allegations of hazards, injuries, or deaths were placed in the appropriate GMP record. The first GMP inspection, in 1984, found "no significant deviations." During

the second inspection in 1984, in response to a complaint of the monitor's failure to sound its alarm, FDA noted that the manufacturer had 17 monitors returned for problems with the alarm.

Subsequently, there were several inspections and other interactions between the manufacturer and FDA about a variety of problems associated with various models of apnea monitor. FDA reported that during an inspection in January 1987, it reviewed all complaints of hazards, injuries, and deaths received since 1985. It was not until a May 1988 inspection, 4 years after the first GMP inspection, that FDA dealt with the reportability of complaints about alarms. By that time, FDA had received a total of 83 medical device reporting regulation reports on the monitor.[24] (See table 1.) More than 88 percent of the reports involved allegations of an alarm failure, including the death of two patients.[25]

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[24]Many of these reports did not originate in complaints to the manufacturer. Reports must be made under the medical device reporting regulation, not only in response to complaints but also whenever a manufacturer acquires information from any source that reasonably suggests that one of its devices may have caused or contributed to serious injury or death or has malfunctioned in such a way that, if the malfunction were to recur, it would be likely to cause or contribute to serious injury or death. Some of the other sources of such information include the manufacturers' own research, testing, or servicing of their devices as well as the medical and scientific literature.

[25]Of 278 reports submitted by September 1989, consisting of 271 malfunction reports and 7 reports of deaths, the manufacturer's tests confirmed that Model 8200 had malfunctioned in 271 of the complaints. However, Aequitron's tests did not confirm that the device had malfunctioned in any of the 7 complaints in which the death of a patient occurred.

FDA did not provide evidence that its inspection procedures included any systematic evaluation of trends in the frequency, type, or severity of complaints involving the failure of alarms that were made to the manufacturer or reported under the medical device reporting regulation. There were also no comparisons of overall complaint rates of alarm failures of Aequitron's Model 8200 to those of other monitors. We believe that the inclusion of these procedures in the inspection program or in the monitoring of medical device reporting regulation reports at CDRH could have served to more quickly identify both problems of underreporting and potentially serious device problems.

CONCLUDING REMARKS

In sum, the evidence from the current case of an apnea monitor is consistent with our earlier finding that there are differences in the interpretation of medical device reporting requirements among device manufacturers and between manufacturers and FDA.[26] In this case, the manufacturer's interpretation resulted in undetermined underreporting of serious problems with a device.

We found that FDA's review of a sample of Aequitron's records determined that at least some complaints alleging that the device

[26]See Medical Devices: FDA's Implementation, p. 62.

was associated with hazards to safety, injuries, or death had not been reported to the agency because of the manufacturer's incorrect interpretation of the medical device reporting requirements.

As a result of FDA's intervention in this case and the device manufacturer's review of its own records,more than 150 additional medical device problem reports were submitted, including 144 reports of device malfunctions. We believe that malfunction reports should be considered as seriously as reports of serious injury or the death of a patient, especially as a preventive measure.

Although FDA has provided all registered device manufacturers with some guidance on reporting requirements in the form of a "questions and answers" document, the example we have presented suggests a potentially serious problem in the manufacturer's interpretation of the requirements and formulation of a reporting policy based on that interpretation, rather than random or isolated failures to report. We believe that device-specific guidance on problem reporting may be warranted for some types of devices.

Our study illustrates the serious consequences that shortcomings in the implementation of the medical devices reporting regulation and subsequent inspection program can have. In this case, FDA did not have information on a number of adverse experiences with the device in question when the agency made

critical decisions with respect to recalls and other regulatory actions. FDA found that this manufacturer's interpretation of the reporting requirements differed from the agency's in ways that put it in noncompliance with the regulation. However, the compliance inspection program did not identify and resolve these differences for a substantial period of time after the regulation went into effect. During that time, FDA did not make valid comparisons of the monitor's problem rates or trends with those of other, similar monitors made by other manufacturers, thus compromising one of the most important uses for data collected under the medical device reporting regulation.

The design of our study precludes generalizing to other devices or manufacturers. However, these findings, taken with our earlier findings, raise a concern that the problem-reporting and inspection issues may pertain to a broader segment of the device manufacturing industry and to the safety and effectiveness of medical devices in general. Therefore, we believe they are worth further attention by FDA.

That concludes my statement, Mr. Chairman. I will be happy to respond to any questions that you or members of the Subcommittee may have.

Mr. WAXMAN. I thank you very much for your testimony and for that report on Aequitron and the experience with this particular medical device, which is pretty shocking, it seems to me, as to what has been happening there.

Mr. Kusserow, you noted the difficulties and lengthy delays FDA experiences taking enforcement actions under the act. Currently, FDA must bring criminal actions to enforce the medical device law. How would the availability of civil penalties assist the FDA in this area?

Mr. KUSSEROW. It would provide a sanction that could be expedited. FDA is constantly frustrated by the fact it does not have the means by which they can take aggressive early action. It would go a long way to enable them to address issues, especially those issues which fall short of criminality, which right now is a big void.

Mr. WAXMAN. Industry representatives have expressed the concern FDA would use civil penalties to enforce the act in an arbitrary and unfair fashion. Is this a reasonable concern in light of the Department's experience with civil penalties under Medicare?

Mr. KUSSEROW. It is totally unreasonable. For example, in the Medicare program, we have had a monetary penalty since 1984. We successfully imposed 600 civil monetary penalties, 90 percent of which—more than 90 percent of which are found to have been resolved between our office and the party in question, without even going to Administrative Law Judge. There have been just a handful of cases where there was even a question as to how it was handled, or whether it was excessive.

From the track record, under the civil monetary penalty provisions, as well as the Program Fraud and Civil Remedies Act, I think it is unfounded. There is adequate due process.

You have an Administrative Law Judge there that acts as a neutral party. I don't think the industry is rational in that point.

Mr. WAXMAN. I was surprised to learn that in the approval of section 510(k)'s, FDA does not review a sample of the product, verify the testing data, or conduct premarket inspections of the manufacturer's facilities, yet 94 percent of medical devices enter the market through this section 510(k) process.

You mentioned FDA recently issued preproduction quality assurance recommendations for medical device manufacturers. These recommendations are not binding, and some industry spokesmen say FDA lacks the legal authority to incorporate the recommendations into the GMP's.

To what extent did problems experienced in the failure of the balloon inflation device result from the absence of preproduction quality assurance controls?

Mr. KUSSEROW. It wasn't, as you noted, not detected during the premarket notification process. Design defects which were not identified during premarket testing or review, ultimately led to a recall. The firm officials said that if they had followed the PPQA recommendations they may have detected the problems early on—they suggest the PPQA recommendations be incorporated into the GMP regulations.

Mr. WAXMAN. You have testified that manufacturers should be required to notify FDA of all voluntary recalls, and that FDA should have the power to order a recall.

Under current law, FDA cannot require an official report a voluntary recall. You state the statutory criteria empowering FDA to order a recall is "so restrictive as to be impractical." Should these issues be addressed in legislation?

Mr. KUSSEROW. I think it must be. There have been so many problems FDA has tried to engage in that they have not been able to because they don't have the tools to do that. I think it does require some congressional action.

Mr. WAXMAN. Mr. Wisler, an important part of H.R. 3095 is a requirement the medical device users like hospitals report deaths and other problems they experience with the use of medical devices. Mr. Benson will testify later this afternoon that this requirement is unnecessary. He points to the FDA's medical device reporting program and the voluntary reporting program directed at health professionals.

Yet, both systems have been severely criticized by industry and reviews by GAO and IG. The fact with respect to the voluntary program, Mr. Kusserow stated that it is underused and does not provide the FDA with adequate or meaningful information.

Your most recent report confirms even FDA headquarters is confused about the MDR system, and manufacturers continue to underreport serious problems.

In earlier reports, you concluded medical device users, particularly hospitals, were not reporting serious problems to the FDA. Does the FDA's two reporting systems always provide earlier warning of problem devices?

Mr. WISLER. No, sir. We think the system does need to be supplemented by information from hospitals in the way you and Mr. Kusserow have described. We think there is a serious amount of underreporting in the system, and probably the only way you will get at that is by having reporting directly from hospitals and distributors in the system.

Mr. WAXMAN. Mr. Kusserow, I assume you agree with that?

Mr. KUSSEROW. I absolutely agree that there is underreporting in the system. It goes back to the same problem, the fact the regulations are vague, and the definitions of malfunction or serious injury are left open to question, and you can drive a Mack truck through those loopholes.

Mr. WAXMAN. Thank you very much.

Mr. Whittaker.

Mr. WHITTAKER. Thank you, Mr. Chairman.

I would like to direct my first question to Mr. Wisler. Mr. Wisler, on page 4 of your testimony, you state that, "Our case study precludes generalizing from these findings and conclusions to other devices and manufacturers."

On page 22, you again state, "The design of our study precludes generalizing to other devices or other manufacturers." So, we can all agree that any one case is the study of a particular circumstance or events of that one company. Statistically, it says nothing about the performance of an industry.

Do you agree?

Mr. WISLER. Yes, sir. The point we are trying to make there in that explanation of our case study was the case study by itself could not be used to generalize, but our previous work, which did

look in a much broader way at the reporting system and at the recalls and the whole system in a much broader way, we can generalize from those studies.

And our case study simply illustrates one of those particular cases.

Mr. WHITTAKER. Mr. Wisler, in your testimony, however, both times you make the point—a case study is not generalizable. You then proceed to make such generalization, such as:

> These findings taken with our earlier findings raise a concern the problem-reporting and inspection issues may pertain to a broader segment of the device industry and to the safety and effectiveness of medical devices in general.

Let me make some comments, if I could. First, if your conclusion in this testimony is based on your February 1989 report, then discuss the methodology and findings of that report in detail so we can make an informed judgment as to its validity.

Second, in your testimony, you state that:

> In its comments on the February 1989 report, the FDA said that the GAO conclusion, that the industry was underreporting, was questionable, and that the FDA's medical device reporting regulation compliance inspection strategy was sufficient to identify compliance problems.

Consequently, your general statements and interpretations concerning the overall implementation of medical device reporting is based on another report which the FDA disagrees with you and has no statistical foundation whatsoever in this detailed testimony you have just given us.

In my point of view, you do this subcommittee a great disservice by presenting an analysis based on such convoluted logic. If you appear before this subcommittee again, I would appreciate it if you would base your conclusions on the results of the study before us, not on reports drafted years ago.

I would like to direct a couple of questions to Mr. Kusserow. Mr. Kusserow, you testified FDA was unable to meet all of it statutory, regulatory requirements for GMP and other inspections, primarily because of limited resources.

Will the administration's budget request for eight fulltime equivalents and $600,000 adequately address the resource limitation?

Mr. KUSSEROW. I can't address that since I don't speak for the administration. I am independent of the Administration.

Mr. WHITTAKER. Mr. Kusserow, does the FDA have any intention of revising the MDR regulation to clarify it and to make it less subject to interpretation?

Mr. KUSSEROW. We have submitted those recommendations to FDA, and they look like they are moving in that direction. We haven't got their final feedback yet. That is still one of the pending issues we are working with them on.

Mr. WHITTAKER. Thank you, Mr. Kusserow. That is all of my questions.

Mr. WAXMAN. The gentleman still has some time. I wonder if he could yield to me? I want to point out the GAO has given us eight reports over 4 years, over the whole question what the industry is doing, and their report now is on a specific case, but I think they

are well positioned after all the work they have done in this area to give us their thoughts, and to generalize it beyond the one case.

I do want to take exception.

Mr. WHITTAKER. That is certainly your prerogative. I personally resent the fact they are coming in here reporting on data that is obviously antiquated.

Mr. WAXMAN. Do you want to respond, Mr. Wisler?

Mr. WISLER. I certainly do defend the previous work we have done in terms of its methodology and in terms of its pertinence for the case here. We are here today reporting on one particular case. I think it is perfectly appropriate to bring in the other evidence which bears on the case. I don't think it is out of date. I think it is very germane.

Mr. WAXMAN. Thank you very much for yielding.

The Chair notes the chairman of our full committee, who has been very active in this area, and without objection, I would like to call upon him.

Mr. DINGELL. You are very gracious. I would like to ask unanimous consent that I be permitted to insert my statement into the record, and would commend you for the vigorous work you are doing to move forward this legislation, H.R. 3095, the Safe Medical Devices Act, which you cosponsored. [See p. 72.]

I would say to Mr. Kusserow, I commend you for being present here. I have had a chance to observe your work at HHS with more than great respect. I want you to understand that.

Mr. KUSSEROW. Thank you, Mr. Chairman.

Mr. DINGELL. I reviewed your testimony. Mr. Wisler, I would like to buttress your comments by saying that the information that our committee developed in concert both with you, the General Accounting Office, and with Mr. Kusserow, has moved me to the firm belief there are problems with regard to the approval of medical devices at the Food and Drug Administration.

Now the problems go more broadly than statutory authority. They relate to inadequate personnel, inadequate budget, lack of appropriate support from the top. The Agency confronts enormous difficulties in terms of inadequate personnel. This bill is a small attempt to cure a penny-wise and pound-foolish program in terms of the handling of device regulation by the FDA.

Your testimony, Mr. Wisler and Mr. Kusserow, and those of your two agencies, have been most impressive to me, but I would like the record to show that it is buttressed by a number of hearings we have held in Oversight in which we found significant abuses, regulatory failures, inadequacy of personnel, failures to notify and comply with the law as it now is drawn, and significant endangerment to the people who use these devices.

These matters must be corrected, and H.R. 3095 is only one small step. Thank you.

Mr. WAXMAN. Thank you very much.

Dr. Rowland.

Mr. ROWLAND. No, thank you.

Mr. WAXMAN. Mr. Nielson.

Mr. NIELSON. I am impressed with what seems to be a parallel of the bill we just passed in the House yesterday, Consumer Product Safety Commission. Where do you draw the line and where should

we draw the line between consumer product safety problems and medical device safety problems?

Are we overloading the FDA too much? There are 7,000 devices, I understand. I am wondering where the line should be drawn. Consumer product safety is to check the product safety. Medical devices are used for medical purposes, but sometimes the problems are exactly the same; the underreporting, the fact you don't have adequate staff to take care of them. Do you see a parallel between the two problems?

Mr. KUSSEROW. I can respond to it by saying I see a parallel. There are differences, but at the same time, there are some parallels. In the case of medical devices, you are dealing with a situation where you have the public health at stake right from the outset, because the device is used to protect the public health and safety.

There are some differences, but at the same time, there are certainly the parallels you describe.

Mr. NIELSON. I was wondering maybe if we buttressed the Consumer Product Safety Commission sufficiently, maybe they could take over some of the areas being handled by FDA.

Mr. KUSSEROW. I think that is probably unlikely, because of the complexity of the products involved in the case of medical devices. The scientific competency necessary to evaluate these products, both in terms of efficacy, and in terms of safety, are so specialized, I think it is unlikely you can move it outside of FDA; quite the contrary. FDA probably needs more resources in this area, so that they can develop greater specialization.

They need to have a resource capability to address the issue, so I think it is not a question of where the responsibility is being placed, it is a question of whether there is adequate resources, commitment, and legal support to allow them to do the job they are mandated by law to do.

Mr. NIELSON. Why are the preproduction quality assurance recommendations not legally binding, in your opinion?

Mr. KUSSEROW. Some of them relate to the fact the way legislation was set up, that created the section 510(k) process. Really, there is a predication on the assumption that you could have an honor system, and therefore, it was moving in that direction.

The problem that we have observed is the Scout's honor system doesn't always work. There are exceptions to the rule, and when those exceptions occur, when you find individual manufacturers that are looking for a loophole——

Mr. NIELSON. Is it because the manufacturer is claiming it is similar to a previous device, or is it because FDA is not checking?

Mr. KUSSEROW. You have a system under section 510(k) process, you have a device that is substantially equivalent to something already in the system. If a manufacturer comes forth and claims it is in fact equivalent, and the claim sounds plausible, then in all likelihood, the section 510(k) approval will take place.

The concerns we have, and the concerns that have been expressed this morning at the hearing is that you can't—you have to have a means by which you can doublecheck it. You can spot check it, but a way in which you can verify that the representations made are totally accurate and consistent with the intent of the law.

Mr. NIELSON. In your opinion, would FDA support these recommendations and regulations? Would they support them in regulations?

Mr. KUSSEROW. I think they need some legislative assistance. I will tell you, it is my perception that FDA sorely needs this and would greatly appreciate having additional latitude in dealing with these things on the premarket side of the equation.

You have to look at both sides of the equation before it goes on the market, and you have to have a surveillance system that is reliable after it is already on the market. In both areas we have been able to document fairly clearly is that FDA should take actions to tighten up the program, some of which are within the powers of FDA, and we are moving to have them tighten up their own procedures.

Mr. NIELSON. Mr. Wisler, we are talking about the apnea program and checking to make sure that children have enough oxygen when they sleep, and if they have dangerously low levels. Are the parents trained well enough to use those, and if not, who has the responsibility for educating them?

Mr. WISLER. That is part of the issue. There has been concern the parents were not well enough trained, and a recent safety alert went out to that effect. Steps need to be taken, information does need to be provided.

Mr. NIELSON. Who has the responsibility?

Mr. WISLER. Partly the responsibility of the parents, but also the firms that provide apnea monitors.

Mr. NIELSON. What about the manufacturers?

Mr. WISLER. Indirectly, in the sense of through the instructional manuals.

Mr. NIELSON. What about the doctor?

Mr. WISLER. Also the doctor, because the doctor is prescribing the use of the monitor, so they have a responsibility to communicate exactly what needs to be done.

Mr. KUSSEROW. If I may add to that, if I could, and point out one of the things we did was to survey the industry to get the industry's perspective, and we found within the industry—and we went to 20 major firms in this field, that they think that some clarification would be helpful for them, too.

I don't mean to suggest that all of the violations of this honor system are as a result of meanness or evil intent, sometimes they are a result of confusion.

Mr. WAXMAN. Thank you, Mr. Nielson.

Mr. Sikorski, you are recognized.

Mr. SIKORSKI. Thank you, Mr. Chairman.

The gentleman from Kansas raised an important issue. I am not quite, I guess, completely comprehending what it is. I think the logic is you can't make conclusions from one case, and that is probably true.

You wouldn't be in the business of drawing broad conclusions, but you have drawn on eight reports, that are at the back here, that detailed repeatedly over 4 years on the underreporting issue.

What bothers me about this whole thing is we in this subcommittee and the oversight investigations subcommittee, when we get around to dealing with the FDA, we hear the political appointees

repeatedly talk about we can do more with less. And to the extent we have more victims of products and drugs that are supposed to be regulated through the FDA and America, they are right, we have more deaths, more injuries and more illnesses to Americans because of less regulation and oversight by the FDA.

I am frankly fed up with this line, people of political lines covering their backsides, and by arguing logically, you can't make your conclusion from one study and one case, and we can do more with the new loaves and fishes that we have.

No one down there that I have seen walks on water, and it is time we get about seriously addressing these issues and not trying to nitpick particular reports.

On this issue, Mr. Kusserow, the Scout's honor system, you have raised a number of disturbing parallels between FDA's regulation of generic drugs and this question of dealing with medical devices.

My feeling is, if the FDA doesn't do the work it is intended to do, you get consumer regulation which is mean and nasty and cruel and very crude. You will get "60 Minutes" and personal injury lawyers making regulatory decisions through processes that are not very comforting to the manufacturers, as well as the consumers in this country.

In the Scout's honor system, we don't have adequate protection or safeguards. Although you have not detected criminal wrongdoing as in the generic drug, can you elaborate on the steps FDA needs to take to avoid a repeat of the generic drug scandal?

Mr. KUSSEROW. We have been doing a whole series of reports. Let me recount, the perspective I have comes from acting as an auditor, we have looked at the internal control systems of FDA with regards to this section 510(k) approval process.

We also, as an investigator have been looking for any kind of trail, signs that there might have been a parallel type of corruption or fraud in that program. As I say, we are relieved thus far the same vulnerabilities we had in generic drugs have manifested the same kinds of problems.

Also, in addition to that, we wanted to get the industry perspective. So we have done a study that has gained their perspective. The kinds of things that are needed are a combination of the above.

Number one, FDA has to make sure their own house is in order. They lack the kinds of written policies and procedures to make sure that they have the approval process being taken in turn and are not taken out of turn.

This was one of the problems we found in the Generic Drug Division, where there was a similar ability to take things out of turn, laying the groundwork for favoritism. We think we need to be sure FDA moves to ensure timely, complete reviews.

Second, FDA lacks a comprehensive quality control program to independently evaluate the adequacy of the reviewed submission. We believe FDA does not have a management information system which will really track workload and productivity of individual reviews.

One of the things we found in Generic Division Two is that reviewers sitting side by side could have a workload factor of 10 difference, and that managers or the supervisors didn't know about it.

There should be some way in which you can level out the workload so you are not swamping one person while someone else is getting a free ride.

We know the FDA has not established controls or written policies that restrict the industry's access to the records or to the reviewers. We believe we need to safeguard the files and have physical security of the offices.

You do not need to have people lobbying their products through the system by having direct access to the records and individuals working on it. I think it interferes with them carrying out their responsibilities.

Also, we found FDA does not have the kind of critical information to make determinations of what is in fact a substantial equivalence, so these are the kinds of things FDA can work on.

The balance of intervening after the fact, really, I think, is going to have to be help from the Congress to provide the tools for FDA to have something between no action and criminal prosecution.

Mr. SIKORSKI. Can I ask one more question? It is on the section 510(k) process. You testified from 1976 to 1988, the 94 percent of the 36,000 medical devices FDA allowed on the market entered through the section 510(k) process, wherein FDA merely determines whether a device is substantially equivalent to a device marketed before 1976.

In carrying out these reviews, it comes as a surprise to me the FDA does not require review of product sample verification of companies asking for premarket inspections of manufacturers' facilities.

Is there a possible explanation why 44 percent?

Mr. KUSSEROW. It is a major problem. I think it has to be addressed not by FDA alone, but it needs the help of Congress to reorder how this process should work. Definitely, it is a major contributory factor.

Mr. WAXMAN. Thank you, Mr. Sikorski.

Mr. Wisler, Mr. Kusserow, we appreciate very much the testimony you have given us, and your recommendations we think are very helpful as we consider this legislation.

We have a meeting of the full committee to consider two pieces of legislation. It is my understanding that the matters under consideration are not going to take a great deal of time.

I would propose now we recess so the members can go to the full committee, and hopefully reconvene here at 11:15 to hear Dr. Wolfe, who will not be able to be with us this afternoon.

After his testimony, we will break and reconvene at 1:30 to complete the rest of the testimony. We would go on to hear from FDA and the other witnesses, but we did inform them we would not have them here until 1:30.

We will now recess for an hour and reconvene in this room at 11:15.

[Brief recess.]

Mr. WAXMAN. Our next witness is Dr. Sidney Wolfe. Dr. Wolfe, we are delighted to have you with us. We also want to congratulate you for being a recipient of the McArthur Foundation Fellowship, recognizing your past and future contributions to public health.

STATEMENT OF SIDNEY M. WOLFE, DIRECTOR, PUBLIC CITIZEN HEALTH RESEARCH GROUP

Mr. WOLFE. Thank you for commenting on the McArthur award, and also for inviting me to testify here.

As you know, we have been involved in the issue of medical devices since the group started 19 years ago. I remember testifying about 17 years ago in the hearings you were involved in.

With me on my left are Brian Wolfman, an attorney with Public Citizen Litigation Group, and Grace Kuo, on my right, a researcher with the Health Research Group, both of whom have played a major contribution, as did Robert Leflar, formerly an attorney on my staff, now law professor, who also analyzed the legislation.

There is no question that things are better, safer for patients, now than when we testified in favor of strong device legislation. However, serious problems still exist. Serious flaws in the legislation, such as not requiring automatic premarket safety testing for all implantable, life-sustaining or life-supporting devices, still allow dangerous devices on the market.

Also, there is a dangerous lack of FDA enforcement under the existing legislative authority. Added with a continuation of deadly, irresponsible behavior by some device companies, hundreds if not thousands of people in this country are killed and many more seriously injured each year by devices which did not need to be so dangerous.

We heard this morning about the Aequitron infant apnea monitors. In August 1989, the same week you introduced this legislation, we wrote to the chairman of the committee, Chairman Dingell, the FDA had found in 35 companies reports of deaths or injuries which should have been reported under the mandatory device requirement, and which hadn't been.

Now, I understand in some cases there may be a difference of opinion between the FDA's and the company's interpretation of the reporting requirement, but I can't believe in every case, 35 companies, involving a number of deaths—7 deaths, 109 serious injuries, 265 malfunctions, and so forth—that in none of those cases was this illegal failure to report a death or injury punishable.

In fact, to our knowledge, FDA has not initiated a single criminal prosecution of any of these companies, and said in response to our report last August that they were just trying to educate the industry by not enforcing the reporting requirements.

We responded they are educating the industry that they don't have to take the law very seriously.

I would like to then turn to a review of most recent class 1 recalls. Class 1 recalls are the most serious ones, and they are ones in which the device, if not recalled, poses the risk of serious adverse health consequences or death.

Between September 20, 1989 and July 4, 1990, FDA was notified of 11 class 1 recalls involving about 53,000 units of recalled devices which had been distributed and were subject to recall.

Only 1 recall plan of these 11 was listed when FDA listed the recall notices as having been completed, although the first of the recalls actually occurred more than 6 months ago.

Seven of these 11 were various resuscitators for children, adults, infants, manufactured by a Texas company, Carrollton, TX, called Life Design Systems. Totalling distribution of more than 42,000 units, the devices used to resuscitate adults, children, infants and neonates in emergency situations, suffer from serious production problems and design problems.

Three resuscitators—three different batches of them—had problems with the swivel elbow. In one, the elbow joint was missing a gusset, an insert used to reinforce a seam, which could lead to breakage during shipping or use.

Another resuscitator, an open swivel elbow, instead of a closed swivel, was assembled onto the main body, causing oxygen to flow through the top of the swivel instead of to the patient.

One-third had a swivel elbow that was "manufactured with a diameter that did now allow the finished device to function properly," and so forth.

We have serious problems in design and manufacture, which could easily lead to the deaths of those people in emergency medical conditions and need to be quickly resuscitated.

Of the 30,000 units, in one of these recalls alone, as of the most recent date, which was in May, that we were aware of 16,000 of them still remained on the market. We have a chart following page 4 of the testimony which looks at just the seven recalls of emergency resuscitators, showing intervals of anywhere between a couple months to a year between when the recall occurred and FDA was notified of it.

I will submit for the record other instances of recalls, and just briefly in the last minute or so go through some of our legislative recommendations for strengthening what you have introduced as the best medical device amendments I think thus far.

As far as the reporting requirements, they are good, but they can be improved by having a deadline by which FDA must issue regulations. Eight years went by before the final regulations on the first mandatory device reporting requirement.

We also believe that in terms of notification, that to ensure the patients may be notified directly by the manufacturer, retailer, medical device user facility, and other individuals or entities, is authorized under section 518.

We believe that authority exists now, but it has not ever been used in the 14 years since it has been in existence. We also believe that manufacturers who have to report to FDA any removals or field repairs undertaken to eliminate health risks or remedy violations caused by the device, should be improved by putting a tight deadline to meet the issuance—for FDA to meet the issuance of implementing the regulations.

Finally, under repair, replacement and refund orders, we think the bill is deficient in that it has no specific recall authority. As we noted in this chart, months, years can go by between the time a company actually issues a recall and FDA actually finds out about it. The company does it slowly, incompletely, sloppily, and thousands of people can be jeopardized by exposure to these devices.

We think there should be specific recall authority that would at least require the FDA to be notified within 10 days of the time that

a company initiates a recall and to have a plan for the recall to occur.

In other words, there needs to be a process to get unsafe devices off the market fast. I guess just the final comment on the performance standards and special controls, we think FDA should have the power to order postmarketing surveillance as a condition to marketing individual class 2 devices. Class 2 is the standard-setting category of more than 1,000 class 2 devices. No standard has ever been set in the 14 years since the law went into effect. At the very least, if something is going to be in class 2, there should be some specific postmarketing surveillance.

Thank you. I will try and answer some questions.

[Testimony resumes on p. 157.]

[The prepared statement of Mr. Wolfe follows:]

TESTIMONY OF SIDNEY M. WOLFE, M.D.
DIRECTOR, PUBLIC CITIZEN HEALTH RESEARCH GROUP
BEFORE THE HEALTH SUBCOMMITTEE OF THE HOUSE COMMITTEE ON ENERGY AND COMMERCE
HEARINGS ON H.R. 3095: MEDICAL DEVICE AMENDMENTS
JULY 17, 1990

Chairman Waxman and members of the subcommittee, thank you for the invitation to testify before the subcommittee on this important set of legislative proposals. With me are Brian Wolfman, an attorney with the Public Citizen Litigation Group and Grace Kuo, a researcher with the Health Research Group, both of whom have made a major contribution to the preparation of this testimony. I would also like to thank Robert Leflar, formerly an attorney with the Health Research Group, for his careful analysis and critique of this legislative proposal.

I. OVERVIEW

In the early and mid-1970's, when legislation to finally regulate medical devices was pending, precipitated by the Dalkon Shield disaster and many other serious but preventable problems with heart valves, pacemakers and other medical devices, we faced an era of failed industry self-regulation. The hope was that by giving FDA much more authority to require safety tests on medical devices before their approval and by otherwise increasing FDA's regulation of this rapidly growing but too often irresponsible industry, there would be a significant reduction in the damage to patients.

There is no question that things are better, safer for patients, now than when we testified in favor of strong device legislation. However, serious problems still exist. Serious flaws in the legislation, such as not requiring automatic pre-market safety testing for all implantable, life-sustaining or life-supporting devices, still allow dangerous devices on the market. Also there is a dangerous lack of FDA enforcement under the existing legislative authority. Added with a continuation of deadly, irresponsible behavior by some device companies, hundreds if not thousands of people in this country are killed and many more seriously injured each year by devices which did not need to be so dangerous.

The tragic story of the Aequitron Infant Apnea monitors, discussed in detail by HHS Inspector General Kusserow and Carl Wisler of the GAO, is instructive in a number of ways in that there are serious questions about its design and its manufacture but we would like to focus on the problem of criminal behavior by device companies accompanied by inadequate FDA enforcement of the now five and one-half year old mandatory device reporting regulations.

On August 3, 1989, we informed Chairman John Dingell that based on documents obtained from FDA, we had learned that during g routine establishment inspections of just a fraction of medical device companies from December, 1985 to June, 1988, FDA found serious, illegally unreported device problems in the files of 35 device companies. FDA inspectors discovered seven deaths, 109 serious injuries 265 malfunctions, 77 cases of malfunction/serious injuries (not specified which) and one design defect.

In one of these 35 companies, FDA found evidence that four infants died and four sustained serious injuries associated with alarm failures on the Aequitron Medical infant respiration/heart monitor.

To our knowledge, FDA has not initiated a single criminal prosecution, as provided for under the device law and regulations, against AEQUITRON or any of the other 34 companies which have needlessly placed patients at risk of death or injury by illegally withholding reports from the FDA. This attitude of lax enforcement only encourages device companies to behave irresponsibly since they know that even if they are caught, they will not be punished. We are told that under the new leadership of Acting FDA Commissioner James Benson enforcing the laws will get a higher priority. We would be pleased to see the evidence. Last year, when we made the list of companies public, the FDA's response to being accused of not criminally prosecuting was that they were in an educational mode, to which we responded that they were educating the industry that they did not have to obey the law.

II. PUBLIC CITIZEN HEALTH RESEARCH GROUP SUMMARY OF FDA CLASS I RECALLS, MEDICAL SAFETY ALERTS, AND SEIZURES: DECEMBER 20, 1989-JULY 4, 1990

Fourteen years after the passage of the Medical Device Amendments (1976), recalls of medical devices are still occurring at an alarming rate. According to a 1989 General Accounting Office (GAO) report on medical device recalls, 48 Class I recalls (involving 233,949 units of defective medical devices) and 1,026 Class II recalls occurred over the six year period between 1983-1988, which amounts to an average of 8 Class I recalls (38,992 units per year) and 170 Class II recalls per year. Already, there have been 11 Class I recalls (involving 53,813 units of defective medical devices) and 164 Class II recalls for the first six months of this year.

The FDA assigns three classes of recalls. Violative products in CLASS I pose the risk of serious adverse health consequences or death. CLASS II recall devices may cause temporary or medically reversible adverse health consequences and

have a remote probability of serious consequences. CLASS III recall devices are deemed not likely to cause adverse health consequences.

According to the FDA Enforcement Report,

a RECALL is the voluntary removal by a firm of a defective product from the market,

a MEDICAL DEVICE SAFETY ALERT is a voluntarily issued communication announced by a manufacturer or the FDA to inform health professionals of a risk of substantial harm from a medical device in commercial use, and

a SEIZURE is an action initiated by the FDA to remove a product from commerce because it is in violation of the law.

This report covers the Class I recalls as well as medical safety alerts and seizures during the six month period between December 20, 1989 and July 4, 1990. The information was found in the FDA Enforcement Report, which is the FDA list of recall, safety alert, and seizure notices. The methodology for the determination of the number of recalls is similar to the method used by the GAO report. Rather than count each device model separately, recalls of a single device type that occurred on the same date and for the same problem is counted as one recall event.

A. CLASS I RECALLS

Between December 20, 1989 and July 4, 1990, the FDA was notified of 11 Class I recalls. In total, approximately 53,163 units of Class I recall devices of various types had been distributed and were subject to the recalls. Only one recall plan was listed in FDA recall notices as having been completed, although the first of these recalls actually occurred more than six months ago. The other ten recall notices list the recall status of the devices as ongoing.

Seven of the Class I recall devices were various resuscitators manufactured by Life Design Systems (a Carrollton, Texas-based firm), totalling a distribution of more than 42,118 units. The devices, used to resuscitate adults, children, infants and neonates in emergency situations, suffered from serious design and production problems. Three resuscitators had problems with the swivel elbow. In one, the elbow joint was missing a gusset (an insert used to enforce a seam), which could lead to breakage during shipping or use. In another resuscitator "an open swivel elbow (incomplete) instead of a closed swivel elbow was assembled onto the main resuscitator body, causing oxygen to flow through the top of the swivel instead of to the patient." A third resuscitator had a swivel elbow that was

"manufactured with a diameter of the elbow and dimensions of the seam or rings that did not allow the finished device to function properly." In addition, another resuscitator "may contain a component (exhalation port) which was mistakenly added to these models which may create too much resistance for an infant to breathe air out," and still another resuscitator may have a rear intake valve that "may dislodge, thereby preventing the unit from delivering air or oxygen to the patient." (The last resuscitator has a distribution of 38,000 units. The firm estimated that 22,000 units remained on the market.) Inadequate manufacturing procedures led to recall of resuscitators with device bodies that "were not properly cured which caused them to tear or disintegrate and caused the device to be unusable," and in another resuscitator "an incorrect glue was used to attach the mini-duckbill housing", which may cause the housing to detach from the device. (See chart on following page.)

An additional recall of a respiratory device involved more defects in design and production. An apnea/respiration monitor (distrib. 1,583 units) manufactured by Electronic Monitors based in Euless, Texas, may fail to alarm as intended due to a defective time delay switch.

In addition, a concentrated liquid form of viable organisms designed to assist in the replacement and maintenance of favorable intestinal bacteria may contain high Klebsiella pneumoniae counts. (Cosmetic Development Systems Inc., Newbury Park, California; distrib. 6,925 bottles)

The remaining two Class I recall devices were manufactured by Ocumed, Inc., based in Roseland, New Jersey. Both the Wet Cote Sterile Wetting Solution for Hard Contact Lens (distrib. 1,437 bottles) and the Valumed Irrigating Eye Wash (distrib. approx. 1,100 units) may contain contamination by Pseudomona cepacia, which could cause a severe eye infection in the user.

For the first six months of 1990, Class II recalls totaled 164, comprising the bulk of recalls reported to the FDA. According to the Class II recalls reported, 139 recalls are listed as ongoing. Twenty-five recalls have been reported as complete.

B. SAFETY ALERTS

In addition to the 175 Class I and Class II recalls, during the first half of the year, the FDA listed nine Medical Device Safety Alerts. Of the nine alerts, only one, the Temporomandibular Joint Implant manufactured by Vitek, Inc., Houston, Texas, reported a firm-initiated ongoing recall of its 12,650 units. The implant "may fragment, delaminate or otherwise be damaged or punctured, [and] debris in the joint from the implants can contribute to progressive bone degenerative changes

LIFE DESIGN SYSTEMS CLASS I RECALLS OF EMERGENCY RESUSCITATORS

	#RECALLED	DATE OF RECALL	DATE OF NOTICE	INTERVAL	#STILL NOT RECALLED AS OF DATE RECALL OR FDA NOTICE
Adult Resuscitator w/Swivel Elbow & Popple Tubing	unknown	09/25/89	03/07/90	6 months	unknown
Adult Resuscitator w/Oxygen Reservoir and Neonatal Resuscitator	187 units	09/02/89	03/07/90	6 months	all *
Adult Resuscitator	22 units	10/05/89	03/07/90	5 months	6 units *
Infant Resuscitator w/Oxygen Reservoir	149 units	03/14/89	03/07/90	12 months	all *
Adult Resuscitator w/Oxy.Res. and Swivel Elbow and Swivel Flex Track Adapter w/Monitoring Port	620 units	09/12/89	03/07/90	6 months	firm estimates none remain on market
Adult Resuscitator and Pediatric Resuscitator	38,000 units	01/17/90	03/28/90	2 months	firm estimates 22,000 remain on market **
Adult Resuscitator w/Oxygen Reservoir	3,140 units	12/18/89	06/06/90	6 months	all

* Company says recall has been completed. ("The Gray Sheet", March 12, 1990, p. I&W-11)

** 16,300 devices not yet located. ("The Gray Sheet", May 14, 1990, p.11)

and to giant cell reaction." The TMJ implant shows the detrimental effects of inadequate preproduction design considerations in that the material was not properly tested before it was implanted.

The other alerts also suffered from problems with such devices

* as a catheter that may have silicone fragmentation occurring at the connectors (Pharmacia Deltec, Inc., St.Paul, Minnesota; distrib. 690 units),

* a Physio Control sensor that may cause burns when used with certain Ohmeda pulse oximeter models (Physio Control Corporation, Redmond, Washington; distrib. 22,092 units),

* a palet that was recalled for the "unexpected collapse of the device while the patient was positioned on the device for a diagnostic procedure" (Siemens Gammasonics, Inc., Hoffman Estates, Illinois; distrib. 633 units),

* a Cobe Membrane Lung Blood Oxygenator, which has disinfectants that may under certain circumstances "be sufficiently corrosive to perforate the metal of the oxygenator heat exchanger in the course of a normal bypass, possibly resulting in a water to blood leak" (Cobe Laboratories, Inc., Arvada, Colorado; distrib. 150,000 units),

* a surgical table for which "the firm informed users that the instructions cover additional safety maintenance requirements for the leg drive shafts friction clutch and inspection of welds" (Smith & Nephew Equipment Group, St. Louis, Missouri; distrib. approx. 10,000 tables),

* a dental air water spray that may present the risk of air embolism or acute emphysema (Midwest Dental Products Corporation, Des Plaines, Illinois; distrib. unknown),

* and an exhalation isolation system that lacks indicators on the front panel to show internal component failure (Infrasonics, Inc., San Diego, California; distrib. 1,836 units).

One notable alert in the May 23, 1990 Enforcement Report involves the Bjork-Shiley 60 Degree Convexo-Concave Prosthetic Heart Valve, which has been found repeatedly for almost a decade to fail due to strut fractures. Almost 80,000 people have the Bjork-Shiley heart valve implant despite the reports of valve fracture and resulting deaths. Shiley, the Irvine, California-based manufacturer, now estimates that all units have been implanted or destroyed.

Not including the distribution of the Shiley heart valve, there were approximately 197,901 units in total of devices for which alerts were issued.

C. SEIZURES

Whereas recalls and alerts are voluntary and initiated by the firm, seizures are actions taken by the FDA. Since the end of December 1989, the FDA has also enacted ten seizures. Seven of these seizures were of latex examination gloves under charges of adulteration (product contains excessive holes) and misbranding (label fails to bear name and place of business of manufacturer, packer or distributor). Cardiac Balloon Dilatation Catheters, Ventilation Tubes for Otology, and Kilip Biological Indicator Ampules were charged with nonconformity with good manufacturing practices for manufacture, storage, and packing.

D. DELAYS IN RECALLS, ALERTS AND SEIZURES

The devices for which recalls, alerts, and seizures were issued cover a nationwide and international distribution with hundreds of thousands of units distributed. The methods used by the companies to inform of recalls or alerts included letters, telephone calls, facsimiles, and FDA approved plans.

In terms of the time frame of the recall process, there appeared to be a gap from the time a recall or alert was announced to the time it appeared in FDA reports. The time varied from one month to four years. For example, three recalls of Theratron Radiotherapy Treatment Units were listed in the March 7, 1990, FDA recall report. However, the recall dates on the devices were September 2, 1986, January 12, 1988, and August 1, 1988. No explanation was listed in the FDA report for the reason for the delay in FDA notification. In other cases, the recall of a device was not listed by the FDA until after the recall had been completed. There was a similar time delay between seizure file and safety alert dates and the FDA listing. But the time it took the FDA to report seizures and alerts generally did not exceed half a year.

The high number of recalls emphasizes the presence of dangerous devices on the market and underlines the importance of effective and prompt regulation and, more importantly, premarket testing. Untested products and malfunctioning, mislabeled devices have resulted in innummerable deaths, injuries, and prolonged hospitals stays at additional costs. An effective system is needed to monitor the recall process and insure that the devices used by hospitals and doctors are safe and reliable and not potentially life-threatening.

E. CAUSES FOR RECALLS

In a recent discussion with a medical device official in the FDA, he told me that it would be an entirely different story if most of the deaths and injuries which occur as a result of the use of medical devices were "unavoidable," that is, if the design, manufacture and use of the devices were as safe as possible. He lamented the fact that we are nowhere near that situation now, as evidenced by the FDA-determined causes of recalls being dominated by design and manufacturing deficiencies. Clearly the problems leading to recall are unavoidable.

A Center for Devices and Radiological Health January 1990 study found that errors or deficiency in design and inadequate good manufacturing practices were the predominant causes of recall of devices from 1983 to 1988.

* Forty-four percent of all recalls resulted from errors or deficiencies in the design of the device during the preproduction phase.

* Forty-seven percent of all recalls occurred in the manufacturing phase.

The report concludes that design-related problems would have been prevented or minimized with the development and implementation of a preproduction quality assurance program; for instance, problems related to process design could have been prevented or minimized if manufacturers had "properly validated the process before initiating routine production." In addition, the report also states that quality problems occurring in the manufacturing phase could have been prevented by the industry's adherence to GMP regulations.

III. ANALYSIS OF HR 3095 AND SUGGESTIONS FOR IMPROVEMENTS

A. Strengthened Reporting Requirements

1. Under proposed sec. 519(b)(1) [HR 3095, p. 2, line 7 on], every "medical device user facility" would have to report to FDA all possibly device-related deaths, life-threatening illnesses and injuries, and device malfunctions likely to cause death or serious illness or injury. Both the scope of reportable events and the scope of entities that must report are broader than in the 1988 bill, HR 4640. In particular, HR 3095 covers not only hospitals, nursing homes, and ambulatory surgical facilities, but also (unlike HR 4640) any "outpatient diagnostic or treatment facility which is not a physician's office." (p. 5 l. 17) FDA would have to issue implementing regulations within a year of enactment. (p. 6 l. 6)

2. The penalty for failure to make a required report would be up to $10,000/day, up to a maximum of $500,000. (Proposed sec. 519(b)(5).) But FDA's authority to levy the fines would not take effect for four years following enactment, and would be triggered only if the agency either reported a lack of substantial compliance by any of the covered categories of medical device user facilities (hospitals, nursing homes, etc.) as a whole, or failed to report to Congress on compliance within the four years.

The problem here is that FDA may determine that a category of facilities (e.g., nursing homes) is as a whole in substantial compliance with the reporting regulation; but once it does so the agency could not assess penalties against individual facilities within that category that flout the law.

3. In a major improvement over HR 4640, reports made under new sec. 519(b)(1) would be admissible in private civil actions against manufacturers, and manufacturers' names would be disclosable. Only the reporting facilities' names would be nondisclosable and the reports would be inadmissible only in lawsuits against them, to avoid incentives not to make the required reports. (p. 3 l. 22; p. 4 l. 15.)

4. A few versions of HR 4640 in 1988 contained language giving FDA power to fine medical facilities up to $50,000 if they retaliated against any of their employees for reporting device problems. (See my article at p. 79 n. 459.) This disappeared from the version of 4640 that passed the House, and is nowhere to be seen here in 3095. It should be returned to this bill.

5. Proposed sec. 519(c) would require manufacturers, importers and distributors to certify annually that reports they sent FDA were complete, or if they sent no reports that they were not aware of any device-related deaths or injuries. Helpful.

6. Proposed sec. 519(d) would require "user tracking" -- that each individual Class III device would have an ID number assigned to it; each manufacturer would have to keep records of to whom each device was sold and when; and each device seller or user would have to keep track of which device goes to which patient, "to ensure that patients who receive such devices can be provided the notification authorized by section 518."

This is good, but could be improved by having a deadline by which FDA must issue regulations implementing the provision. There would clearly be benefits in requiring the information to be centrally accessible.

Proposed section 519(d)(1) can be strengthened by making crystal clear that each individual device, as opposed to each model or device type (e.g., 21 mm 60 degree Shiley cc valves), must be assigned a separate identification number. This is

probably already the intent, but it is not clear from the wording.

Proposed section 519(d)(1)(B) should require manufacturers to maintain records of the date of sales throughout the chain of distribution of the device, and the date the device was actually manufactured, not simply the date it was first sold to anyone in the chain of distribution.

Proposed section 519(d)(2) is potentially very important because it appears to provide a method whereby notification under section 518 could be efficiently carried out. It needs to be made more specific. It is too vague simply to say that everyone in the chain of distribution should maintain records "to ensure that patients who receive such devices can be provided the notification authorized by section 518." This potentially would allow FDA to require information concerning only physicians (as opposed to patients), since section 518 authorizes physician notification as well patient notification.

We would therefore suggest the following substitute: "to ensure that patients may be notified directly by such manufacturer, retailer, medical device user facility, and other individual or entities as authorized by section 518."

Moreover, it would be useful if the statute itself spelled out that the manufacturer is required to obtain name, address, telephone number, device model number, identification number, etc. with respect to each patient who receives a Class III device.

Given FDA's do-nothing approach on this issue, we think it is crucial that FDA be given a short period of time to issue regulations on this provision (say, 6 months) and also to issue regulations explaining the parameters of its discretion under section 518(a)'s notification provisions. In short, once it is determined that the facts of a particular case meet the findings required by section 518(a) of the Act, there should be little or no discretion for FDA not to require notification.

Finally, the user tracking provision is good in that it mandates the collection of information. But it does not make any attempt to manage that information. Obviously, it makes little sense to collect information in very different places (i.e., some information collected by the manufacturer, some by a distributer, some by the doctor, etc.), which the bill seems to allow. There should be a provision which requires the manufacturer to collect this information, and place it in a central, easily accessible registry. The manufacturer of the Class III device should then have to tell FDA where and how this information is organized and how it can be accessed. Under the current bill, even though

there is "user tracking," we are doubtful that the system could respond quickly to a public health emergency.

7. Distributors would be made subject to the existing reporting regulations. FDA should have done this long ago, as GAO recommended; but the agency hasn't moved on it.

8. Manufacturers would have to report to FDA any removals or field repairs undertaken to eliminate health risks or remedy violations of the act caused by the device (proposed sec. 519(d) p. 22). This provision should be improved by giving FDA a tight deadline to meet for the issuance of implementing regulations. All reports, by statute, about removal or field repairs would have to be filed in 10 days.

B. The Premarket Clearance Process

HR 3095 would phase out over a five-year period the "substantial equivalence" review, by which FDA has allowed (in unaccountable fashion) the marketing of the vast majority of new devices. Approximately 34,000 of the 36,000 medical devices or device modifications marketed after 1976 following FDA review have not had premarket approval based on required pre-market testing. They have merely to notify FDA. This 510K phase-out is a laudable goal. But it must be accompanied by some other means of letting FDA sort through all the thousands of new devices without requiring PMA applications for them all. The process would begin by sweeping some current Class III devices out of that class, as follows:

1. Manufacturers of transitional Class III devices would have to submit all known adverse safety and effectiveness data within a year after enactment. Within two more years, FDA would do a notice-and-comment procedure either keeping these in Class III or downclassing them (proposed sec. 520(l)(5), p. 16).

* Downclassification decisions could be challenged only through reclassification petitions, by "any person adversely affected." (p. 17 l. 15.) This needs to be changed to "any interested person," so that HRG, for example, could file such a petition in case (e.g.) we file a comment against a downclassification and FDA disagrees.

* 2. Manufacturers of Class III devices that are on the market because of substantial equivalence reviews (as opposed to having full-fledged premarket approvals) would have to submit all known adverse safety and effectiveness information to FDA within about 4 years after enactment. Before the end of the fifth year, FDA would go through a similar notice-and-comment process for keeping those devices in Class III or downclassing them. (Proposed sec. 515(i), pp. 14-15.) Here too, "any person adversely affected" needs to be changed to "any interested person." (p. 15 l. 16)

3. During the 5-year phaseout period for the substantial equivalence review process, FDA would operate under a new statutory definition of "substantial equivalence" (proposed sec. 520(m), pp. 11-12) essentially the same as the informal definition FDA is operating under now. There would be several major improvements in the process though:

* (a) Manufacturers submitting 510(k) premarket notifications would have to certify to FDA that they were including all known adverse safety and effectiveness information (proposed sec. 513(f)(3), p. 13);

* (b) FDA would have to issue a safety and effectiveness information summary to the public, with each order finding a device substantially equivalent (p. 12 l. 18);

* (c) a determination of substantial equivalence would be a judicially reviewable order (p. 18, l. 12).

Most importantly, whatever restructuring of 510K is done Congress must figure out how to build in an accountability mechanism into any restructuring, or the process would continue to fail.

C. Repair, Replacement & Refund Orders (p. 22)

* This bill is considerably better than HR 4640 -- it does what needs to be done, without the compromises we saw last time. It simply abolishes the existing requirement that before FDA issues a repair, replacement or refund order, the agency must determine that "there are reasonable grounds to believe that the device was not properly designed and manufactured with reference to the state of the art as it existed at the time of its design and manufacture" (current sec. 518(b)(1)(A)(ii)).

This bill is deficient in that it has no specific recall authority. Section 515(e) of the law (withdrawal of a PMA) is a very deliberative process in which the agency considers whether a Class III device ought to come off the market.

There ought to be the authority in FDA to require a manufacturer to cease production and to recall all devices upon the issuance of an administrative order (or by use of some similar procedure) if the device poses a "significant risk to public health which cannot be reduced absent the remedy provided herein."

In other words, there needs to be a process to get unsafe devices off the market fast.

D. Performance Standards and "Special Controls"

1. Like HR 4640, this bill cleans up the procedure for promulgating performance standards. It becomes a notice-and-comment process with the manufacturer having an opportunity to request reclassification (pp. 20-21).

2. This bill tries to put some additional content into Class II by renaming the class "Special Controls" instead of "Performance Standards," and defining "special controls" to include not only performance standards but also "development and dissemination of guidelines, recommendations, and other appropriate actions by the Secretary." (p. 19)

As you can see, this doesn't do much except possibly give FDA some undefined new power. FDA can already develop guidelines and issue recommendations, whatever class a device is in, and who knows what "other appropriate actions" are? It's hard to imagine something this vague getting out of the Congress -- it's too easy a target.

If extra content needs to be put into Class II -- and it does, if the classification is to have any practical meaning at all -- we would suggest a mixture of specific additional agency power, and a less-general-sounding generality. For example:

(a) Give FDA the power to order postmarketing surveillance as a condition to marketing individual Class II devices. This could include user tracking (see proposed sec. 519(d), discussed above).

(b) Take the language from sec. 520(e) on restricted devices, which FDA has never implemented, and use it here to permit FDA to control individual Class II devices. (FDA can already do this for Class III devices, by order not regulation, under sec. 515(d)(1)(B)(ii).) Put in something like this:

The Secretary may by order require that a Class II device be restricted to sale, distribution, or use

(a) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(b) upon such other conditions as the Secretary may prescribe, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

E. Premarket Approval Requirements

1. Advisory committee review of PMAs would become discretionary with FDA, unless the device's sponsor requested it (p. 25 l. 4). We would prefer advisory committee review to remain mandatory, in order to put a hold on FDA enthusiasm about new devices and to get a public record made. Possible exception: "if the Secretary finds that the information in the application which would be reviewed by a panel substantially duplicates information which has previously been reviewed by a panel appointed under section 513."

* 2. HR 3095 provides (a bit obliquely) that FDA, when considering a PMA from one sponsor, can use data in other existing PMA files to determine the new device's safety and effectiveness. (Proposed sec. 10(a), p. 24 l. 10-13.) This is contrary to FDA's current position, and the new provision should spur competitiveness.

F. Miscellaneous

1. The banning process is speeded up by abolishing advisory panel review and the informal hearing. (p. 25 l. 16-19.)

2. FDA would have an obligation to carry out education and training to minimize people's exposure to device hazards. (Proposed sec. 520(n), p. 24.)

3. FDA would get authority to regulate the remanufacture of devices (alteration etc.). (p. 23, bottom.)

G. Exports of Hazardous and Unapproved Devices

* One other ground for improvement of this bill would be to apply better controls to the export of devices that are unapproved or have been subject to regulatory action in the U.S., as we discussed.

Thank you.

Mr. WAXMAN. Thank you very much, Dr. Wolfe, for your testimony and your leadership on this issue all these years.

I want to ask you some specific questions, because we want to get answers for the record. Industry has expressed concern FDA would apply new civil penalty authority in an unfair, arbitrary manner. Is this a reasonable concern?

Mr. WOLFE. Right now, as Mr. Kusserow mentioned this morning, the choice is criminal penalties or nothing. And whereas we believe there are a number of instances in which, clearly, penalties clearly should be leveled, if only to make the rest of the industry aware of the fact that they are criminals by withholding certain kinds of information, civil penalties, I think, would be an important adjunct to FDA's enforcing of the law.

I don't think it would be arbitrary. If anything, FDA's record of imposing any kind of penalties on industry is too slight, rather than too heavyhanded. So, we strongly support adding civil penalties; disagree with the FDA that this would create a problem.

Mr. WAXMAN. The FDA is unenthusiastic about the user reporting requirements in the bill. They believe the two existing reporting systems and periodic factory inspections provide adequate postmarketing surveillance.

Do you agree?

Mr. WOLFE. If you have got 10,000 devices out on the market and problems start occurring, and the only person who is required to report them is the company, if they find out about them, it may take two or three or four times longer than necessary for the FDA to get the critical number of reports to say, take it off the market or modify it.

By requiring hospitals to automatically report these problems, as this legislation does, you will speed up the time that it takes to find out enough about a dangerous device to take it off the market.

The FDA, out of one corner of its mouth, admits only a tiny fraction of the actual injuries and deaths that are occurring are getting reported. On the other hand, turns off the possibility of supplementing significantly by requiring hospital reports of deaths and serious injuries, these reports.

I mean, certainly it can be said FDA hasn't maximally used the mandatory device reports it has gotten from industry to earlier do something, but that is not an excuse for saying we don't want more reports.

Large numbers of people's lives would be saved if the larger number of reports coming from hospitals got to the FDA in a timely fashion, as the law would require, and allow them to take action more quickly.

I just don't believe that right now, every hospital is automatically reporting every injury that occurs to the company. Because if they aren't, that means this amendment would make a big difference.

The hospitals are worried about product liability issues, and if they don't have to report them, they may not report them. I think it is an important advance. It was in the legislation a couple years ago, it is long overdue.

Unlike drugs, most of the devices that really have serious life-threatening consequences are at least put in in the hospital or used

in the hospital. And heart valves are carried around, as are pacemakers, but a much larger proportion of the damage that occurs as a result of faulty medical devices is recognized by hospitals than I think is the case for drugs.

It is a very important advance, I strongly disagree with FDA's statement.

Mr. WAXMAN. FDA has asked the subcommittee to consider a provision eliminating the requirement listing the color additives used in medical devices. They argue the safety of color additives used in medical devices that come in contact with the body is adequately assessed within the context of the review process.

Do you agree?

Mr. WOLFE. I certainly don't. We went through this kind of issue—in fact, Mr. Schultz litigated the case involving taking away certain cosmetic dyes. Most of them are safe, a few of them caused cancer. They only cause "a little bit of cancer," but when a large number of people use something, it may be a little bit is a lot of cases of cancer.

There are enough dyes for cosmetics or foods, or in this case medical devices, that are safe, that don't cause cancer and don't have side effects, that we can limit the ones that are used to those dyes.

If something is too unsafe to be in a food as a food additive or food color additive or in a cosmetic, it should also be too unsafe to be in a medical device. In fact, unlike food dyes, which you swallow and which may or may not be absorbed in some cases, here they are being implanted in the middle of the body, and the tissue has ready access to the dyes.

So, I think there should not be a double standard, particularly for things that are so often implanted.

Mr. WAXMAN. If the legislation were revised to retain a modification of the section 510(k) process, would you support making such approvals conditional on FDA reviewing, one, product sample; two, verifying test data; and, three, inspecting a manufacturer's facilities?

Mr. WOLFE. As was brought out this morning in the discussion of section 510(k) by Mr. Kusserow, those three items, although clearly within the current legislative and regulatory framework, aren't paid attention to a lot of the times.

And certainly that has made the section 510(k) process, which is flawed, period, because of the misuse of the phrase, substantially equivalent, even worse. I would certainly support, during the period in which the section 510(k) period is phased out, which I think ultimately it must be, I think all devices must be in class 1, 2 or 3, as intended by the law.

We shouldn't be allowing what amounts to 30-plus-thousand devices to get on the market without premarket testing. I think those three provisos could certainly be applied seriously, which they haven't been before, at least during the phaseout period.

It is possible, not likely, once those were applied, the section 510(k) would be made somewhat better, but I don't think it would be made sufficiently better, so it didn't ultimately need to be phased out entirely.

Mr. WAXMAN. FDA is opposed to the requirement in H.R. 3095 that the Agency prepare summaries of safety and effectiveness for all substantial equivalents determinations. They believe preparation of summaries are unreasonably resource-intensive, and information regarding substantial equivalents determinations is already publicly available through the Freedom of Information Act.

Do you agree that information documenting the decisionmaking process in section 510(k) determinations is available under the Freedom of Information Act?

Mr. WOLFE. Some is, but not enough. I think the best way of looking at it is to look at the situation with respect to prescription drugs. When a prescription drug is approved as safe and effective enough to be on the market, a summary basis approval is available through the FDA. There is a package of information reflecting the views and analysis of the FDA people who reviewed the drug.

It is a package that may be half an inch, an inch thick. It requires no additional work, because these documents were already prepared. If something comparable to that were available, which I suspect it isn't in most cases of section 510(k) approval, we would be satisfied. I think what one would get now is a very cryptic, inadequate explanation as to why this device is viewed safe enough, not endangering the public enough, so it can escape the premarket safety studies that often should be there.

I think if FDA were forced to disclose the basis upon which it so easily grants section 510(k) status, that there would be a certain amount of embarrassment. It would also provide an ability of another company or public interest group to challenge the validity of the section 510(k) determination.

I think that when the Agency cries "paperwork burden," too much, what it is saying is either that its Xerox machine is broken or they haven't really provided the documentation sufficient to answer these questions.

If there isn't documentation, that is a problem in and of itself. I believe, hopefully, somewhere in the FDA already exists documentation to tell whether or not this was done frivolously.

Mr. WAXMAN. Thank you very much.

Mr. Nielson.

Mr. NIELSON. If the medical device bill passed by the House last year had been in place, would that have addressed most of your concerns?

Mr. WOLFE. No, it would not.

Mr. NIELSON. Did you support that bill last year?

Mr. WOLFE. We did not. We strongly opposed it.

Mr. NIELSON. You opposed it because it was not strong enough?

Mr. WOLFE. The FDA has had a tradition——

Mr. NIELSON. That is not my question. I said FDA opposed it because it was too strong. You opposed it because it wasn't strong enough.

Mr. WOLFE. I just want to answer your question and define "strong". FDA believes it has the authority to do at least a number of things that were in that bill and in this bill. The fact is, it hasn't done them, and one of the tugs between the legislation and the way the administrative Agency functions is how much has to be mandated so there isn't any choice.

When FDA took 8 years to put out a regulation requiring deaths to be reported by device manufacturers, they had the authority, but they weren't told they have to get this out in a year.

I think a number of things we would support in this legislation it to tighten the grip as to how much discretion FDA would have. FDA was claiming 2 years ago it was pushing them around too much. I think they need to be pushed around.

Mr. NIELSON. You mentioned phasing out section 510(k) is a laudable goal, but it can't be done immediately. But you also say recurring PMA's for all devices is not feasible. If that is the case, what recommendation do you have for a more equitable system?

In other words, section 510(k) is too easy and premarket too expensive and time consuming. Is there something in between?

Mr. WOLFE. FDA claims amongst the spectrum of section 510(k)'s that it approved on one end, they do require a fair amount of data and at least is close to the PMA, premarket approval kind of requirement. I guess what we are saying is there aren't enough at that end of the spectrum, and when you start getting at that end of the spectrum, I am not sure if it is anything other than a semantic difference.

Technically, it is section 510(k). I think the original scheme—which is class 1, labeling and so forth; class 2, performance and standards; class 3, premarket testing—it is still good.

Within the latitude of premarket testing requirements, which there should be for everything, I think one can specify a lot of data or less data. That would be a safer scheme than allowing this sort of paper checkoff game that happens very often with the section 510(k)'s.

Mr. NIELSON. Do you think the requirement to obtain the name, address, phone number, device bottle number, of each patient who received a class 3 device, do you think that is a successive requirement?

Mr. WOLFE. I don't. We have it for cars. I think many more people are notified when there is a car recall, often over something much less serious than what devices are recalled for. It does not make sense in this age of microcomputers and whatnot, we would have a registry for everyone who owns a car that needs to have some problem or another fixed, but not for everyone who has a heart valve or pacemaker.

I think by definition, class 3 is a serious enough class we need to do a much better job for having a registry. Right now, there is an amazing problem going on concerning the Charlotte heart valve, the 50,000 to 60,000 people walking around with the valve, and many of them, judging from calls to Congressman Dingell's office and Congressman Waxman, and our office, don't know if they have a good one or bad one.

Mr. NIELSON. Is it feasible for the manufacturer to notify the patient than the physician?

Mr. WOLFE. It is feasible.

Mr. NIELSON. Do——

Mr. WOLFE. I think they can do it by hospital records and insurance records. I think in the future, though, that it should be anticipated at the beginning, and any time someone has something implanted that might get in trouble—I mean, a significant enough

proportion of pacemakers break or fail, that there should be a registry. That has been started finally for pacemakers, but hasn't extended to other categories of medical devices.

It is much easier and less expensive and simpler to do it at the front end than have to play catchup, as is occurring with the heart valve now.

Mr. NIELSON. Do you think it might be a chilling effect on the medical industry, for example, if there were premarket approval required for everything, some wouldn't bother with medical devices, or do you think there would be plenty of medical devices going through that process?

Mr. WOLFE. We are not saying premarket approval should be required for everything. There are a large number of things in class 1 which is no premarket. There are over 1,000, 1,100 in class 2, some of which I suppose could be arguably in class 1, but a lot of them go up to class 3.

I don't think there is a chilling effect. I distinctly remember the chilling effect concern expressed by cardiac surgeons and others who paraded before the subcommittee when legislation was pending in 1974, they were saying we don't need regulation, we don't need a law. We have a $14 billion industry which I think has increased sevenfold in size between the time that the legislative hearings were held in 1973 and now.

I can hardly imagine that there has been a chilling effect or there would be by further tightening things up. What I think would happen is you would save thousands of people from being killed. Save a lot of needless injuries and needless property liability litigation, and you would reward those companies who have been doing a good job.

It is not most companies doing a terrible job any more than it is most doctors practicing bad medicine. A small handful, which literally get away with murder, have been doing a very inadequate job. This Life Designs Co. I mentioned before, FDA has at least forced them to stop all shipment of all products of their company.

In Japan, which competes very successfully with our country in many ways, when a company does something like that, they board up the company, close it down. We need more of that here in the device areas, so the good companies can thrive.

Mr. NIELSON. I know your company is the one that issued the report, but you got GAO involved in the apnea monitoring program. Congratulations for that. May I ask a question? Is the Aequitron apnea monitor better, worse, or similar to other apnea monitors on the market?

Mr. WOLFE. We noticed that 1 of the 11 recalls that occurred in 1990 already is another apnea monitor. It is a sort of critical life device, as is the case with many of these.

Mr. NIELSON. How does the Aequitron compare with other monitors?

Mr. WOLFE. I don't think there is any side-by-side comparison. There have been failures of the Aequitron—and I can't remember the name of the other one—it is listed in our testimony. Whether they are all bad, and all should be improved, or whether the Aequitron is worse, it is too critical an area to allow the kinds of things to happen, including failure to report things.

Whatever is wrong with the Aequitron, I think things would have been fixed more quickly if the FDA had been notified more quickly.

Mr. WAXMAN. Thank you, Mr. Nielson.

And Dr. Wolfe, thank you for your testimony. We are now going to recess, and we will take panel 3 of this hearing at 1:30.

[Brief recess.]

Mr. WAXMAN. The subcommittee will come back to order.

Our next witness is James Benson, Acting Commissioner of the Food and Drug Administration. We are pleased to welcome you and your colleagues to this hearing. Your prepared statement will be in the record in full. We would like you to limit your oral presentation to no more than 5 minutes.

STATEMENT OF JAMES S. BENSON, ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY DAVID WEST, DEPUTY DIRECTOR, OFFICE OF DEVICE EVALUATION; JOHN VILLFORTH, DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH; AND MARGARET PORTER, CHIEF COUNSEL

Mr. BENSON. It is a pleasure for me and my colleagues to appear before you and this subcommittee to discuss our views on H.R. 3095, the Safe Medical Devices Act of 1989.

Regulating a universe of 80,000 different makes and models of products, whose complexity, sophistication and risk potential vary greatly presents unique challenges to FDA. We have attempted to interpret the medical device amendments in a manner that best protects the public from unsafe and ineffective medical devices.

Mr. Chairman, let me address the legislation at hand, which is what I think you are fundamentally interested in. I believe we share some common perceptions with respect to the need for legislation.

Many of the proposed changes are positive and long in coming. For example, H.R. 3095 would codify FDA's policy on substantial equivalence. This would ensure FDA's interpretation of the act is clearly understood by the regulated industry.

FDA has developed policy on substantial equivalence based on the intended use and technological characteristics of the new device and preamendments device to which it is being compared. A device is substantially equivalent only if it has one, the same intended use and technological characteristics as a device to which it is being compared, or two, the same intended use as the device to which it is being compared, but different technological characteristics which do not raise new issues of safety and effectiveness.

The Agency to date has been able to defend its section 510(k) program, however, the Agency wants Congress to codify its interpretation in order to avoid an adverse court decision.

H.R. 3095 would also redefine class 2 to broaden the controls applicable to those devices to provide reasonable assurance of their safety and effectiveness. The bill would give FDA discretion to apply one or more special controls to a given device problem. These special controls could include mandatory standards, educational ef-

forts, guidelines, voluntary standards, and other activities tailored to solve a specific problem.

In those instances where a mandatory standard is deemed to be an appropriate solution, the bill would simplify the procedures for establishing a standard.

Section 10 of H.R. 3095 would amend the portion of the act that stipulates how a device's effectiveness may be demonstrated. We assume the intent here is to modify or eliminate the statutory prohibitions on the use of data from manufacturers' PMA's to approve or reclassify another's device.

The Administration supports efforts to relax this prohibition, as it prevents the Agency from reclassifying mature technologies or significantly altering, when appropriate, PMA requirements for class 3 products.

Countless resources are wasted by industry and FDA in requiring full premarket approval for the same or similar devices time and time again. The Agency would have the flexibility to adjust regulatory requirements as its knowledge and experience with a given technology evolves.

And I just want to stress the importance of being able to reclassify products as our confidence is gained, so we can keep the freight moving via both the PMA and section 510(k) process.

In my limited time I would like to talk a little bit about some of the disagreements.

We do have significant disagreement with you on the provisions of H.R. 3095 that would establish a comprehensive device problem reporting program for hospitals, outpatient facilities and nursing homes, which number in the thousands.

A user reporting system of this magnitude is neither necessary more feasible.

Section 4(a)(3) appears to be an attempt to preclude use of the section 510(k) program for preamendment class 3 devices.

The intent as well as the effect of this language is unclear. Our section 510(k) program provides the Agency significant flexibility to evaluate similarities and differences between devices to determine their relative safety and effectiveness. Only those devices that truly present significant differences are required to undergo premarket approval.

This proposed change would lengthen product review times, raise health care costs, and impede the introduction of new technologies to the market.

In sum, while there are many positive changes contemplated by H.R. 3095 that I would like to see enacted, the onerous nature of the user reporting provisions and increased PMA review due to the proposed changes to section 510(k) program dictate that I cannot support the bill as drafted.

We stand ready to work with the subcommittee to draft a bill that is acceptable and that achieves our mutual goals.

Thank you for letting me present these views and I would be happy to answer your questions.

[Testimony resumes on p. 180.]

[The prepared statement of Mr. Benson follows:]

STATEMENT OF

JAMES S. BENSON

ACTING COMMISSIONER

FOOD AND DRUG ADMINISTRATION

Mr. Chairman,

I am James Benson, Acting Commissioner of the Food and Drug Administration (FDA) within the U.S. Public Health Service of the Department of Health and Human Services. It is a pleasure for me and my colleagues to appear before you and the Subcommittee to discuss our views on H.R. 3095, the "Safe Medical Devices Act of 1989."

For those of you who may be unclear as to what the current law requires, and with the indulgence of those for whom this may be repetitious, I would like to begin with a brief summary of the Medical Device Amendments and how we have put them into practice.

Background

In the last few decades, scientific advances have catapulted the industrialized world into a high-speed technological revolution. Materials and manufacturing processes developed in conjunction with the exploration of space, as well as the computerization of nearly every facet of daily life, have produced major "spin-off" advances in other areas, including medicine. As a result, clinicians have at their disposal an ever increasing array of new and sophisticated medical devices. With their introduction came the realization that existing regulatory controls needed strengthening in order to assure that new technologies were safe and effective before entering the marketplace. As a result, the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) formally

initiated the regulation of an ever-growing medical device industry. Before enactment of the 1976 law, FDA's authority was limited to actions that could only be taken after a medical device had been introduced into interstate commerce and then only when a device had been found to be adulterated or misbranded. In essence, the burden of proof was on the Government to show that a marketed device was unsafe or ineffective. Currently, when FDA believes a product to be violative, FDA can recommend seizure of the product or injunction or prosecution of the violator.

Passage of the Medical Device Amendments changed dramatically the way FDA regulated medical devices, with the inception of a regulatory scheme that provides for the evaluation of devices before they are permitted into commerce.

By design, the Medical Device Amendments embrace a comprehensive regulatory scheme intended to protect the public from unsafe and ineffective devices. At the same time, the 1976 law is structured to guard against excessive governmental restrictions which might inhibit innovation in the development and advancement of biomedical products.

The 1976 law created a three-tiered classification system that is based upon the degree of risk posed by a device. At the outset, all "preamendment" medical devices (those marketed before passage of the Amendments) were placed into one of three classes. FDA carried out this classification process with the assistance of advisory panels, comprised of outside scientific and medical experts.

Of the more than 1,700 generic medical devices that fall within our regulatory jurisdiction, roughly 700 have been placed in class I. Devices in this class pose the least health risk and are subject to what the law refers to as "general controls," which include requirements for manufacturer registration and product listing, adherence to good manufacturing practices, and prohibitions against misbranding and adulteration. Class I controls also apply to class II and III devices. Almost 800 devices were placed in class II and are subject to performance standards, which have been interpreted as mandatory Federal standards. The remaining 200 or so devices were designated class III. These devices, many of which are at the cutting edge of technology, pose the greatest potential health risk. Manufacturers of class III devices, generally, must comply with the law's premarket approval (PMA) requirements, which require the use of valid, scientific evidence to provide reasonable assurance of a device's safety and effectiveness prior to marketing.

According to the regulatory scheme, post-amendment devices are automatically Class III unless they are determined to be "substantially equivalent" to either a preamendment class I, II or III device or a post-amendment device that has been reclassified into class I or II. "Substantial equivalence" is determined through review of a notification of intent to market a device under section 510(k) of the Act. Manufacturers are required to submit such notification to FDA 90 days prior to marketing.

The law also authorizes FDA to impose certain requirements for human testing of experimental devices, for product manufacturing and quality control, and for monitoring and reporting of adverse device-related incidents. In addition, the

Agency is empowered to compel manufacturers to correct misbranded and adulterated devices and to remove them from the market if they endanger the public health.

Regulating a product universe of this size -- which includes at least 80,000 different makes and models, whose complexity, sophistication and risk potential vary greatly -- presents unique challenges to FDA. We have attempted to interpret and administer the Medical Device Amendments in a manner that best protects the public health from unsafe and ineffective medical devices.

The Criticism Task Forces

After several years of implementation of the 1976 law, FDA became increasingly aware of a gap between Congressional expectations and the Agency's ability to fulfill its mandate.

Beginning in 1984, the Agency undertook a wide-ranging internal review of policies and procedures affecting virtually every major portion of the device program. This activity was carried out by 11 task forces charged with analyzing the validity of criticisms leveled at the Agency and determining the extent to which the public health was being compromised by perceived or real deficiencies. The task forces were also directed to propose alternatives to improve FDA's capability to protect the public health from unsafe or ineffective medical devices and to enhance the quality and productivity of the new product review process, without compromising FDA evaluations of device safety and effectiveness. The result of this effort was a compilation of thorough and thoughtful recommendations for policy, procedural and administrative changes that

streamlined our programs and fostered consistent and reasonable application of laws and regulations.

The Criticism Task Force effort marked a major turning point in the medical device program and led to the development of a program reform strategy that was incorporated into an FDA-wide Action Plan. The Plan's principal objective was to map out a "blueprint" for modernizing the Agency's capacity to deal with complex regulatory, scientific, and clinical issues. One of the basic tenets of the Action Plan, as it related to medical devices, was the need to reform, within the existing legal framework, outmoded or unnecessarily burdensome requirements related to bringing products to market. Working through this nonlegislative approach fostered management innovation and imagination. It also required making hard decisions regarding resource allocation, program direction, and the prioritizing of activities. Examples include:

- elimination of redundant or unproductive operating procedures;
- development of guidance for product application requirements for both industry and Agency staff;
- establishment of an internal system for prioritizing devices based on factors such as known risks, reports of adverse effects, extent of product usage, and potential impact on public health;
- development of guidance distinguishing between significant and non-significant risk clinical studies; and

- development of guidance limiting indiscriminate use of experimental devices while, at the same time, allowing for "compassionate" applications.

These changes have resulted in shortened product application review times, more consistent review criteria and significant reduction of application backlogs.

The Agency also improved and strengthened its postmarket surveillance efforts into a postmarket product management concept. This concept goes beyond postmarket surveillance to include problem analysis and identification; risk assessment; solution identification and implementation; and evaluation.

These efforts have contributed to the availability, safety and effectiveness of important, new technologies that have a significant, beneficial impact on the public health, as well as the timely identification and resolution of problems associated with marketed devices. Despite significant accomplishments, the Agency remains committed to further progress in implementing the Amendments in the manner intended by Congress.

H.R. 3095

I will now address the legislation at hand.

H.R. 3095 is comprehensive medical device legislation that proposes to amend most major device program activities. Most significantly, it would:

- require hospitals, ambulatory surgical facilities, outpatient diagnostic and treatment facilities, and nursing homes to report deaths, life-threatening illnesses and injuries, and malfunctions attributed to devices to FDA and the manufacturer;

- codify FDA's current policies regarding determinations of substantial equivalence under section 510(k) and require summaries of safety and effectiveness supporting 510(k) determinations;

- require either reclassification or premarket review of all preamendment class III devices and transitional devices; and

- redefine class II devices as devices for which "special controls," rather than mandatory standards, can reasonably provide assurance of safety and effectiveness, and substitute the current complex standard-setting process with simple notice and comment rulemaking. "Special controls" would include mandatory performance standards as well as voluntary standards, educational activities, guidelines and other activities.

Areas of Agreement

Mr. Chairman, the Criticism Task Force effort I spoke of earlier not only highlighted various shortcomings in FDA's regulation of devices, but also brought into sharp focus certain weaknesses in the law itself. I believe we share some common perceptions with respect to the need for legislation to amend the Medical Device Amendments. Many of the proposed changes are positive and long in coming. For example, H.R. 3095 would codify FDA's policies on substantial equivalence. This would ensure that FDA's interpretation of the Act is clearly understood by the regulated industry.

Current law and the legislative history of the Medical Device Amendments give very little guidance as to what constitutes "substantial equivalence." FDA has developed policy on substantial equivalence based on the intended use and technological characteristics of the new device and the preamendment device to which it is being compared. A device is substantially equivalent only if it has a) the same intended use and the same technological characteristics as the device to which it is being compared, or b) the same intended use as the device to which it is being compared, but has different technological characteristics, which do not raise new questions of safety and effectiveness, and evidence has been submitted that demonstrates that the device is as safe and effective as marketed devices. According to this policy, a device's technological characteristics are considered different from those of the device to which it is compared if there is a significant change in materials, design, energy source, or other features.

FDA's 510(k) policy enables us to balance public health concerns and the realities of Agency resource constraints. Integral to maintaining this balance is the Agency's ability to require clinical data under section 510(k) to establish that a postamendments device is as safe and effective as the preamendments device to which it is being compared. Compliance with a request to submit clinical data to support claims of substantial equivalence in a 510(k) is important to both the Agency and manufacturers because such compliance helps avoid the very costly PMA (premarket approval) process, which is inappropriate where such data can demonstrate equivalence.

The Agency to date has been able to defend its 510(k) program and our General Counsel advises us that there is reasonable support for FDA's interpretation and application of the statute. Because of the importance of the program, however, the Agency wants Congress to codify its interpretation in order to avoid an adverse court decision, even if that decision were eventually reversed. Any adverse court decision regarding FDA's 510(k) program could needlessly force products into the PMA process, a much more expensive and time-consuming route.

In addition, FDA would propose adoption in statute of the following limitation on predicate devices: that a manufacturer may not rely upon, as a predicate device, a device that had been removed from the market at the instance of FDA or a device that had been deemed misbranded or adulterated by a court.

Class II Standards

H.R. 3095 would also redefine class II to broaden the controls applicable to these devices to ensure their safety and effectiveness. It seeks to eliminate the requirement for mandatory performance standards, saving time and resources, as standards are costly to develop, update and enforce, and frequently are not the optimal solution to a problem. The bill would give FDA discretion to apply one or more "special controls" to a given device problem. These special controls would include mandatory standards, and would also include educational efforts, guidelines, voluntary standards and other activities tailored to solve a specific problem. In those instances where a mandatory standard is deemed to be an appropriate solution, the bill would simplify the procedures for establishing a standard.

In addition, I urge clarification, possibly in report language, that standards developed could apply to one aspect of device performance across device categories (i.e. horizontally) as well as to all aspects of specific device categories (i.e. vertically). In some instances such horizontal standards may be more efficient. For example, since many devices are electrically powered, one can foresee the applicability of a general electrical standard for devices. The trend toward increasing international harmonization of regulatory requirements makes this approach more desirable due to the activities of the European Economic Community.

Certification/User Tracking

H.R. 3095 would require manufacturers, importers and distributors to certify annually the number of MDR reports filed with FDA. This would provide the Agency an additional "check" with which to assess compliance with the MDR regulation.

H.R. 3095 would also require manufacturers of class III devices to affix an identification number to each device and maintain necessary records to facilitate patient notification under section 518 of the Act. (Individuals or entities that sell or use such devices would also have to maintain such records). This would ensure a critical link between manufacturers, health professionals and patients that often is inadequate or lacking altogether. The Agency would want flexibility in administering the requirement to take into account the level of risk.

Notification

H.R. 3095 would also require manufacturers, importers and distributors to report to FDA any "removals or field repairs" of a device undertaken to eliminate a risk to health or remedy a violation of the Act. We have interpreted this to mean mandatory notification of recalls. Currently, manufacturers are not required to notify FDA of such actions. This change would enhance our postmarket surveillance efforts.

Streamlining Procedures

H.R. 3095 would also streamline procedures by making discretionary, advisory panel referrals for PMA applications, reclassification petitions, petitions to amend, revoke or establish a standard, and actions to ban a device. The bill would also make discretionary, opportunities for hearings when establishing a standard, banning a device and reclassifying a transitional device. Currently these are mandatory and needlessly delay final determinations on product approvals and regulatory actions.

Use of Safety and Effectiveness Data

Section 10 of H.R. 3095 would amend the portion of the Act that stipulates how a device's effectiveness is determined. According to section 513(a)(3)(A), effectiveness is to be determined "...on the basis of well-controlled investigations..." The bill would qualify that effectiveness be determined "...on the basis of well-controlled investigations, irrespective of the sponsor of the investigations ..." The intent, as well as the effect of this language is unclear. We assume the intent, at least in part, is to circumvent the statutory prohibitions contained in sections 520(c) and (h) of the Act on the use of data in a manufacturers' PMA to approve or reclassify another's device.

The Administration supports efforts to relax this prohibition, as it prevents the Agency from reclassifying mature technologies or significantly altering, when appropriate, PMA requirements for class III products. Countless resources are

wasted, by industry and FDA, in requiring full premarket approval for the same or similar devices time and time again. The Agency should have the flexibility to adjust regulatory requirements as its knowledge and experience with a given technology evolves.

Other: Color Additives

FDA would favor inclusion of a provision eliminating the requirement for listing of color additives used in medical devices. The safety of color additives used in medical devices that come in contact with the body is adequately assessed within the context of the review processes, in which all of a device's components and properties are evaluated.

Areas of Disagreement

Mr. Chairman, there is significant agreement between us, however, several provisions of H.R. 3095 present serious concerns for FDA.

User Reporting

Section 2 of H.R. 3095 would establish a comprehensive device problem reporting program for hospitals, outpatient facilities and nursing homes, which number in the thousands. A user reporting system of this magnitude is neither necessary nor feasible.

FDA has developed a postmarket product management concept that integrates FDA's knowledge of, and experience with, medical devices to enable the Agency to anticipate and resolve, rather than react to, device problems. Postmarket product management is a critical component of our overall device program, since premarket testing, which occurs under highly-controlled conditions, cannot address many relevant questions (e.g. user experience, rare effects and device lifetime questions) which emerge only after a device is marketed to the general population. In addition, by law, only a relatively small percentage of devices go through premarket approval.

A key component of postmarket surveillance is the Agency's MDR program. As mentioned previously, under MDR manufacturers of medical devices must submit reports of deaths, serious injuries and malfunctions associated with their devices to FDA. FDA receives approximately 16,000 reports annually and has collected over 85,000 reports in its database since 1985, the first full year that MDR was operational. FDA also has other means through which it obtains device experience information, however, the bulk of it is obtained through MDR.

While certain modifications in our problem reporting systems might enhance our postmarket surveillance efforts, the broad-based, comprehensive approach taken in H.R. 3095 would serve only to inundate the agency with data of unmanageable quantity, dubious quality and enormous expense. Our preferred approach is to fine tune and improve our current systems, which already have a firm foundation and provide a basis for focused action. We already have in place a voluntary reporting program directed at health professionals, as your bill would do.

Elimination of Preamendment Class III Devices From Determinations of Substantial Equivalence

Section 4(a)(3) of H.R. 3095 appears to be an attempt to preclude use of the 510(k) program for preamendment class III devices. The intent, as well as the effect, of this language is unclear. Our 510(k) program provides the agency significant flexibility to evaluate the similarities and differences between devices in terms of their technologies and applications to determine their relative safety and effectiveness. Only those devices that truly present significant differences are required to undergo premarket approval. We believe that was the intent of Congress. This approach provides for protection of the public health without unnecessarily slowing the introduction of new products. It also allows the Agency and the industry to make most effective use of their resources, since premarket approval is much more expensive, time-consuming and resource intensive. This proposed change would lengthen product review times, raise health care costs, and impede the introduction of new technologies to the market.

Summaries of Safety and Effectiveness

Section 4 would also require preparation of detailed, publicly available summaries of safety and effectiveness for all substantial equivalence determinations. Development of publicly-available summaries would be very resource intensive for the Agency, slowing product approval activities with no concomitant public health gain. Information regarding substantial equivalence determinations is already publicly available through the Freedom of Information

Act. FDA makes approximately 5,000 substantial equivalence determinations each year. At the same time, we have developed and implemented a program that ensures that 510(k) determinations are properly documented.

Special Interest Provision

Section 12 of H.R. 3095 would exempt electro-convulsive therapy devices from the changes contained in the bill. Without addressing the merits of the particular provision, I want to stress that we oppose special interest legislation in most instances. Efficiency and equity require that regulatory problems, when they exist, be addressed systematically and not in a patchwork fashion.

Conclusion

In sum, while there are many positive changes contemplated by H.R. 3095 that I would like to see enacted, the onerous nature of the user reporting provisions and the provision eliminating preamendment class III devices from the 510(k) program dictate that I cannot support this bill as drafted. I stand ready to work with the Subcommittee to draft a bill that is acceptable and can achieve our mutual goals.

Thank you for the opportunity to submit my views. I will be happy to answer any questions you may have.

Mr. WAXMAN. Thank you very much. We look forward to working with you as well.

Let me ask you some questions for the record.

Does FDA make determinations of the relative safety and effectiveness of devices when making substantial equivalence determinations?

Mr. BENSON. Before I answer that, may I introduce my colleagues?

At my left is Dr. David West. He is the Deputy Director of our Office of Device Evaluation. I think you know Mr. John Villforth, who is Director of the Center for Devices and Radiological Health.

To my far right is Dr. Ann Holt. Ann is the Acting Director, and normally the Deputy Director, of our Office of Compliance. And you know Margaret Porter, who is FDA's Chief Counsel.

I wanted to do that earlier, but I didn't want to do it in the 5 minutes.

Mr. WAXMAN. I am not going to let you take up my time. I am resetting the clock.

Mr. BENSON. Okay.

Mr. WAXMAN. My question is, do you make determinations of relative safety and effectiveness of devices when making substantial equivalence determinations?

Mr. BENSON. I think the key term there is "relative," and, David, I would like you to go ahead and answer that, if you would, please.

Mr. WEST. As you know, with the PMA's, the PMA product has to stand on its own feet in terms of safety and effectiveness. With the product going through the section 510(k) process, the key word is "substantial equivalence" to a product already on the market, and we do make determinations of relative safety and relative effectiveness of the new product to one that is on the market.

And we consider basically two factors. One is the intended use, and the other is the design—that is, technical characteristics—of the product. We look at design and, if necessary, performance of the product in making that determination.

Mr. WAXMAN. Could you provide for the subcommittee the number of section 510(k) notifications which required the submission of clinical data since 1988, and we will hold the record open for that.

[The information follows:]

In fiscal year 1988, FDA received 5,536 section 510(k)'s. Four thousand four hundred and thirty-two of these were found substantially equivalent. Of these, 230 at 5.2 percent, were found substantially equivalent on the basis of clinical data.

Mr. WAXMAN. You testified section 4 of the bill is unnecessary because information regarding substantial equivalence determinations is already publicly available through the Freedom of Information Act.

Is it your position that preparation of written summaries on the safety and effectiveness of substantial equivalence determinations is unnecessary because FDA will release internal Agency documents which document the basis of the section 510(k) determinations?

Mr. BENSON. I think that is correct.

The concern we have is strictly one of the resources required to create and release the summaries. The concern is not releasing them. The concern is in generating them, and the concern is the resources that it takes to do that.

Do you want to cover that?

Ms. PORTER. We would also, under existing law, obviously not release any information that is commercial confidential or trade secret.

Mr. WAXMAN. What information would you release under the Freedom of——

Mr. BENSON. It depends. We would release what was requested if it didn't violate either the proprietary or commercial confidential guidance.

Mr. WAXMAN. Would that information that you would release tell us about the safety and effectiveness of the device?

Mr. BENSON. The question is to what extent would it represent a summary.

And, David, let me refer back to you.

Mr. WEST. Virtually the entire file is released, less the proprietary information that has to be purged for protection. That file would include any data, preclinical as well as clinical data, that would have been required of the manufacturer and submitted in the file, as well as our review and our decisionmaking process for that file.

Mr. WAXMAN. We earlier heard from Mr. Kusserow about the need for preproduction quality controls.

Can you explain why such a substantial percentage of medical devices are recalled for design deficiencies, and why FDA feels preproduction controls are appropriate?

Mr. BENSON. Let me underline the fact that I think over time we have had a chance to study the recall profile and learn more and more about manufacturing processes and so on. This is a concern that has grown, and we strongly support the need to do more in the preproduction area.

The common sense answer is that production is only half the battle. If you have designed a poor product and your manufacturing processes are perfect, you are going to perfectly replicate a poorly designed product.

Both sides of the issue need to be looked at.

John, would you like to further that?

Mr. VILLFORTH. I think our analysis would support the fact that there are numerous situations, almost half the time, when the problems of recall are identified by the manufacturer not having put enough attention to a design that would be robust enough or hard enough to withstand particular problems. And the existing Good Manufacturing Practices regulation, as Mr. Benson said, does not address that problem.

Mr. WAXMAN. Would it be helpful if legislation clarified the FDA's authority to require preproduction quality controls as part of the GMP's?

Mr. BENSON. I would like Margaret to answer that, please.

Mr. WAXMAN. How about yes or no?

Ms. PORTER. How about a maybe? Obviously, I wouldn't want to state that we don't have the authority to do something that we

would like very much to do. And we obviously have got a considerable amount of authority to impose GMP requirements that deal with manufacturing processes. So, we would want to be able to exercise our authority administratively to the fullest possible extent.

Having said that, we haven't really tested the outer limits of that authority, and, as you know, we have got a proposal out now asking for comment on our efforts to impose additional controls.

So, certainly additional explicit authority couldn't hurt, but I wouldn't want that to be viewed as a concession that we can't move in this area.

Mr. BENSON. I think that is mostly yes.

Mr. WAXMAN. That is the way I heard it.

Mr. Whittaker.

Mr. WHITTAKER. Thank you, Mr. Chairman.

Mr. Benson, H.R. 3095 phases out the section 510(k) approval mechanism. The stated purpose of the provision, of course, is to enforce the requirements that the most dangerous device be improved for safety and effectiveness.

In your opinion, does the section 510(k) process insure safety and effectiveness?

Mr. BENSON. Let me make sure we are operating under the same premise. I think what gets phased out is the use of the section 510(k) process for bringing class 3 products on market that are similar to preamendment class 3 devices, not all devices.

I think that is the premise, as I understand it, and I think that is what I would like to answer, if I may.

The concern that we have is that if the objective of Congress and of the law was eventually to get over that hump then we shouldn't continue to have large numbers of preamendments devices on the market. So we need time to be able to either reclassify those devices, because they shouldn't be in class 3 or call for PMA's for those products, in fact, so that is our goal.

And we have, I think, made substantial progress toward that goal. We have systematically identified the preamendment devices that we think are the highest risk. We have called for PMA's for those devices. We have spread them across the various expertise in the center, that is, the divisions that have the responsibilities, so we didn't put them all in one group.

But my concern about the phase out is that it will happen faster than our resources can keep up. That is the concern.

Mr. WHITTAKER. Could you give this committee an approximate idea of the expense involved for a PMA?

Mr. BENSON. Sure.

I can, but I think maybe Dave or John would rather.

Mr. VILLFORTH. The expense to the Government in terms of the staff time reviewing it is, on average, 1,200 staff hours to review a PMA application.

Mr. WHITTAKER. Would you have any estimation of what the product manufacturers' expense would be?

Mr. VILLFORTH. No, I don't. I am sure that would vary depending on the nature of the product. We have a lot of products that are relatively simple, for example, contact lens saline solution.

Other products are incredibly complex, like some of the newer imaging devices, or lithotrypsy devices. They require a lot more intensive review by the manufacturers.

Mr. WHITTAKER. I appreciate your comments to that regard, because I have not followed this issue too closely in the last few months. However, I did have some involvement with it some years ago, and obviously with my background, I know contact lens solutions are fairly elementary in terms of the detail and complexity, as compared to a pacemaker, yet contact lens manufacturers are required to jump through the same loops. I am very concerned about this and remain to be so.

Now, I understand there has been some form of agreement, maybe this bill will help address this problem. There were companies in America that became multimillion dollar profit companies at the sacrifice of competitiveness for the smaller companies that were trying to jump through the loops and yet didn't have the financial resources to be able to do that. So it virtually granted immunity through the regulatory process to these giants who had the resources to comply with all of the provisions.

So I am very concerned that the consumer is getting the short end of the stick. I want to go on record to be the first to say that there is a legitimate safety concern that should be addressed. I want to give you the full authority, and will support funding that when that comes about.

The regulatory process can be used adversely for profit motives by some bigger companies at the sacrifice and harm of smaller ones.

Mr. BENSON. I think we agree with you, at least certainly conceptually.

I think in the instance of contact lens, as I wanted to stress in my opening statement, one of the things that would help a lot is if we were able to have an easing of some of the requirements that stop us from reclassifying. Whether it is contact lenses or just about any other product, the act of reclassifying allows us then to assure, I think, safety and effectiveness under the section 510(k) provision. I think that is a very important thing to do.

I think Bob Britain testified this morning, if I am not mistaken. I haven't seen his testimony or haven't read it, but I think if we were able to reclassify a product as complex as nuclear magnetic resonance whatever the proper term is these days, that is a very complex instrument.

We were able to reclassify that because the industry worked together toward providing the data so that there wasn't a block on the use of proprietary information for that purpose.

And that is a major road block for us. It is not so much that we don't want to get on with the reclassifications. It is when we can't get at proprietary data and use it, not to make it public, but to use it ourselves. Then we are precluded from accomplishing the reclassification.

That is a very important issue, not only for contact lenses, but many other products.

Mr. WHITTAKER. Thank you, Mr. Benson.

Mr. WAXMAN. Thank you, Mr. Whittaker.

Mr. Scheuer.

Mr. SCHEUER. Thank you, Mr. Chairman.

We heard earlier up to 94 percent of medical devices coming on to the market enter through the section 510(k) process. Many of these section 510(k) determinations involve dangerous class 3 devices.

Is it true, in reviewing these determinations, the FDA doesn't even look at a sample of the product or verify the company's testing data?

Mr. BENSON. We may or may not verify—and I think you mean by verify, do our own testing.

In general, in the vast majority of cases, we would not do our own testing. That is valid.

Mr. SCHEUER. And do you ever look at the product? Do you ever see the product?

Mr. BENSON. We would, under our GMP program, when we routinely go in and do the good manufacturing practices inspection.

Mr. SCHEUER. Inspection of what?

Mr. BENSON. Of the firm, of the plant, which would include looking at the records that the company has on the product. But we would not perform tests on the product itself, in the vast majority of cases.

We simply don't have the resources to be able to do that.

Mr. SCHEUER. Wouldn't it make sense for you to at least—physically look at the product, look at the medical device. Are you making these decisions based solely on a narrative description of the device and how it is supposed to work?

Mr. BENSON. Let me let David continue to answer that.

Mr. WEST. In the section 510(k) process, we can look at the design of the device, its specifications, and if that is sufficient, for a very simple device, we can understand its performance. That might suffice.

If the device is more sophisticated and the narrative engineering description of the device is not sufficient, we may feel that we need engineering, bench testing, animal testing, or human clinical data to understand how the device performs and how well it performs, then we will ask for that in the section 510(k), and we will get that information.

If upon analysis we suspect the veracity of that data, we do have the capability of requesting a bioresearch monitoring inspection, in which inspectors can go to the firm, obtain the raw data and we can verify the data.

Mr. SCHEUER. What I am asking is, don't you ever look at the products, examine it physically?

Mr. WEST. If from an engineering discussion and description we cannot understand it, then we can request a sample be submitted, but it is usually just to help the reviewer develop a concept of operation. It is not to test the device.

Mr. SCHEUER. Wouldn't it help the reviewer to develop a concept of the operation to look at it in real life terms, look at the product?

Mr. WEST. If the reviewer feels he has to see the device he or she will request the device to look at. That happens very, very seldom.

Mr. SCHEUER. All right.

Next question.

The Inspector General has testified in support of granting FDA the authority to seek civil penalties for violation of the act.

Apparently the IG feels that FDA would benefit from an intermediate sanction some place between nothing and the ultimate criminal penalties.

Now, the industry has expressed the FDA would exercise the civil penalty in an unfair or arbitrary fashion.

Based on everything you know, is this a reasonable concern?

Mr. BENSON. I don't think it is a reasonable concern.

I personally favor civil penalties. We have had civil penalties under the Radiation Control Act since 1968. That system has worked very well. I don't think—we overused that provision for medical devices. I think it would be a valuable provision. And I think we would use it carefully and would not overdo it.

Mr. SCHEUER. Thank you, Mr. Chairman.

Mr. BENSON. I think Ms. Porter would like to add to that answer.

Ms. PORTER. I would like to echo what Mr. Benson said.

The Department, as you know, has had increasing experience with civil penalties as an intermediate sanction in the Medicare and Medicaid programs. I think so long as it is not used to substitute for criminal prosecutions, it, again, becomes an additional weapon in our arsenal.

We think it is appropriate and we don't think there is any evidence FDA would misuse it.

Mr. SCHEUER. Thank you, Mr. Chairman.

Mr. WAXMAN. Mr. Sikorski.

Mr. SIKORSKI. We heard FDA only requires manufacturers undergo inspections once every 2 years. The Inspector General notes in the report half of the manufacturers meet this timeframe, 11 percent of the class 2 manufacturers have never been inspected.

We also have heard FDA inspections are adequate. They often do not involve more than one of a manufacturers' many product lines.

If additional resources were available, would you recommend more frequent or timely inspections?

Mr. BENSON. Yes.

Mr. SIKORSKI. If funds were available, would you like to see an inspection force established devoted solely or primarily to medical devices?

Mr. BENSON. This is a debate we get into in the Agency. My own view is very clearly we need both kinds of people.

As the technology continues to evolve, I think it is critical we have people that are as sophisticated as that technology, and can go in and do various things.

At this point I don't think a device group, per se, that would do nothing but devices and nothing else but devices, is the way to go. But I certainly would like to see more technical expertise in all of the technologies that we are responsible for, and I think there are many common areas. Software, for example, is something that transcends many of our product areas beyond devices.

Mr. SIKORSKI. So if I understand correctly, you think it would be good to specialize, not necessarily have a device only group, but a group that can hit the technical aspects, the technological advancements, and as that transfers into other lines, be available to do that as well?

Mr. BENSON. Exactly.

We must keep up with the state of the technology, absolutely must.

Mr. SIKORSKI. Conserving FDA resources is obviously a concern of your side of the table and our side of the table.

Can you give us suggestions how the PMA process can be streamlined or be made more effective?

Mr. BENSON. I think, regarding the PMA process itself, we have taken some steps towards streamlining it. I think that it represents a relatively small percentage of the products that go to market, so I think that what has been more consuming of my attention over the years on this issue is to make sure that we don't lose the ability to bring products on the market via the substantial equivalence route. That is where most of the energy has gone.

Let me ask David, who is directly involved in this, to comment on your question.

Mr. WEST. I think there are two things that clearly would make the PMA process less onerous for ourselves. One, that we be given greater discretion as to when we could take a PMA to an advisory panel. And, two, I think also the issue we raised before, or Mr. Benson did in his opening remarks, that is being able to open up the PMA data bases, so we can transfer our knowledge, so to speak, from device to device, and we don't make each manufacturer reinvent the wheel every time they come through with their own version of the product.

I think opening up the data bases and making them publicly available would be a major step.

Mr. SIKORSKI. Sir?

Mr. VILLFORTH. I was going to make an observation.

In addition to this—your question was addressed to the process, there is an area which can improve the PMA process and our resources that are expended on it and that is to make sure the manufacturers understand clearly what is necessary to come in with a good quality application.

If that occurs, the amount of staff time that we invest with a well-done scientific application is reduced. We can get it out fast and it will use a minimum amount of resources. If we can invest a little more to help the manufacturers better understand what is necessary I think we will get a return back by having better quality applications in.

Mr. SIKORSKI. Have you gone to a data base? The GAO this morning talked about management data base.

As you may know, or not know, my mother-in-law worked for the FDA for almost a quarter of a century. And I talk to a lot of your employees on a regular basis, and they tell me you are comparing devices in this case A with device B and I think you touched on it in your second point, open up the data base. There is no data base that is computerized that you can punch it up and compare.

Have you gone to that or going to that?

Mr. WEST. When I was referring to the data base, I was referring to the data that a manufacturer would generate and acquire for his particular product, whether it be laboratory testing or whether it be clinical testing. And we would like to see that data be made available.

Mr. SIKORSKI. How about internally to FDA, to people that are there having to compare?

Mr. WEST. We do this regularly with section 510(k) products. It may not be on a sophisticated computerized basis, but we have an institutional knowledge.

Mr. SIKORSKI. I understand that. There are big files and big junk closets and you pull it down and it's—if you go on our attack submarines a few years ago, you find people manually doing comparisons from big telephone book size manuals of sounds, sound waves that could be done split second by a computer that was 5 years old at that point. That has changed.

But you are still manually comparing very complicated stuff that could be done by computer, and free your people up to do—are you going to that?

Mr. BENSON. Let me take a shot at answering that.

I think I know what you are referring to, and back in 1982 we established a goal to essentially set up that kind of data base within the center so we could track, not only approvals and equivalences, but also when we ran into a problem, one group could tap into a computer base someone else had generated, whether it was our science group or educational or product approval or compliance. We are scattered all over the map, as you well know.

It would also be very nice as a further goal to bring the field into that data base so when they looked at something they could call it up on the computer, know what the status——

Mr. SIKORSKI. The inspector we talked about earlier is going out to do something, may not be a specialist, but he or she could pull up something.

Mr. BENSON. That is exactly right.

And being able to tap into that kind of universal system was the goal.

We, unfortunately, because of resources and because of technical complexities, have backed away from that. We still have that as a long range goal, and we have done a lot to automate our data bases internally.

Mr. SIKORSKI. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Sikorski.

Mr. Benson, all the panelists, we thank you very much for your testimony.

Our next witnesses represent the medical device industry. Alan Magazine is vice president of the Health Industry Manufacturers Association, accompanied by Edwin Allen, HIMA, general counsel; Stephen L. Ferguson is counsel to Cook Group Inc., medical device manufacturing company from Bloomington, IN; Robert Britain is representing the National Electrical Manufacturers Association; and J. Dan Bailey, is president of the Contact Lens Manufacturers Association.

We are pleased to welcome you to this hearing. Your written statements are in the record. We would like you to limit your oral testimony to 5 minutes.

STATEMENTS OF ALAN MAGAZINE, PRESIDENT, HEALTH INDUSTRY MANUFACTURERS ASSOCIATION, ACCOMPANIED BY EDWIN H. ALLEN, GENERAL COUNSEL; STEPHEN L. FERGUSON, COUNSEL, COOK GROUP INC.; J. DAN BAILEY, PRESIDENT, CONTACT LENS MANUFACTURERS ASSOCIATION; AND ROBERT G. BRITAIN, MANAGER, DIAGNOSTIC IMAGING AND THERAPY SYSTEMS DIVISION, NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

Mr. MAGAZINE. Good afternoon, Mr. Chairman, and members of the subcommittee. I am Alan Magazine, president of the Health Industry Manufacturers Association. I welcome the opportunity to discuss changes to the medical device law. Since I have been at HIMA for only a few months, I have asked Eddie Allen, HIMA's general counsel, to assist me in responding to your questions.

The more than 300 companies that belong to HIMA account for 90 percent of the sales of medical devices and diagnostics in the United States. These companies are the innovators and developers of modern medical technology.

Contrary to popular belief, device and diagnostic manufacturers are not all large. Two-thirds of HIMA's members are small businesses with annual revenues of $20 million or less. While manufacturers introduce a number of breakthrough products each year, the vast majority of products are late generations of products that have steadily been refined as a result of rapid incremental improvements over several years.

In 1989, FDA identified seven breakthrough technologies that it cleared for marketing. But more than 5,000 other products were cleared for marketing during the same period. The vast majority of these were reviewed under the premarket notification authority included in section 510(k) of the Food, Drug and Cosmetic Act, a provision well-suited for the review of medical technology that is developed through incremental change.

HIMA companies are committed to the safety of medical devices and diagnostics. We think, however, that the definition of safety is unduly narrow if it is restricted to mean preventing harm to patients and health care providers. We believe that the concept of safety should be more encompassing and include the concept of permitting new, more effective technologies to be available to patients as rapidly as possible.

We think that the appropriate approach is to give FDA legislative latitude which allows its personnel to keep unsafe products off the market while expediting the review of new technologies that can improve the health of Americans.

HIMA believes that FDA currently has a great deal of authority to regulate medical devices. Before FDA is given additional authority to regulate devices and diagnostics, it should be established that FDA needs that additional authority. If it is established that FDA does need additional authority, resources to allow the Agency to carry out that new authority should be provided.

In its report for the 1989 fiscal year, the Office of Device Evaluation at the FDA Center for Devices and Radiological Health noted that the total number of product submissions it received increased 15 percent from the previous year. At the same time, the number

of its full time equivalent employees decreased by more than 8 percent.

HIMA is concerned that adding unnecessary new authority will not only adversely affect the review process for new products, but postmarketing compliance activities at the center as well.

As you know, HIMA has participated with this subcommittee in the development of medical device legislation for more than 4 years. Beginning in 1986, HIMA staff participated in briefing sessions arranged by the subcommittee staff with a view toward developing the first changes to the 1976 medical device amendments.

In 1988, HIMA's board of directors, reversing a longstanding position that no change to the 1976 legislation was needed, made public its acceptance of H.R. 4640, legislation that passed this subcommittee and the full Energy and Commerce Committee in June and the full House in July 1988.

Although HIMA believes that H.R. 4640 can be improved, HIMA will support virtually all of that bill again this year. We believe that there are a number of provisions in the 1988 bill that will improve the regulatory process of FDA.

The most significant provision in that respect is one that codifies the current practice at FDA with respect to section 510(k) premarket review. Inaccurately described by some as a loophole allowing a rubber stamp approval of medical products, section 510(k) is a provision that allows FDA maximum flexibility in protecting both aspects of safety I described earlier.

The section 510(k) review process is uniquely suited for technology that is improved through incremental refinement. The section 510(k) authority allows FDA to scrutinize a product to a degree commensurate with its sophistication and complexity, requesting clinical data when necessary.

As was noted this morning by Mr. Kusserow and Mr. Wisler, 94 percent of products cleared for marketing under the section 510(k) processes are class 1 or class 2 products; 75 percent of section 510(k) clearances are for modifications to products already marketed by the submitting manufacturer; of the 6 percent of total section 510(k) clearances that are for class 3 products, many are supported by clinical data comparable to data that would have to be provided in a premarket approval application.

The revision to section 510(k) contained in the 1988 House bill codifies current review practices and explicitly provides FDA the discretion to require a product applicant to submit clinical data.

The provision also requires the publication of that data shortly after the product was reviewed. But most significantly, the 1988 bill allows the Agency to use for the determination of substantial equivalence, products that have come on the market since 1976, thus permitting the introduction of advanced technology without having to establish absolute comparability with devices that were introduced more than 14 years ago.

We recognize the subcommittee's concern about underreporting of incidents involving devices by providers of health care. Although we disagree about the magnitude of this problem, we will support the provision addressing that concern in the 1988 bill.

Additionally, we recognize that FDA has not been able to establish performance standards for class 2 devices. We support the pro-

vision in the 1988 bill giving FDA discretion in developing those standards.

HIMA also supports the provision amending section 518(b) of the Food, Drug, and Cosmetic Act concerning the standard for repair, replacement, and refund. Although section 518(b) in the current law has never had to be used, we believe the revision in the 1988 bill is acceptable.

The only provision in the 1988 bill HIMA cannot support is that concerning the application standard for premarket approval. That provision would authorize FDA to waive certain premarket approval [PMA] application requirements.

HIMA is concerned that this provision will stifle innovation. Companies will be reluctant to invest the substantial sums necessary to bring a new product to market for fear that once approved, FDA will abbreviate the premarket approval requirements for the subsequent applicants, making it impossible for the innovator company to recoup research and development costs.

Finally, I would like to make some remarks about a matter that gives the medical technology industry some concern. In recent weeks, the Department of Commerce has identified a disturbing trend concerning the development of medical technology. In a report released by the department just 2 weeks ago entitled "Emerging Technologies: A Survey of Technical and Economic Opportunities" the following conclusions were made:

One, the United States currently leads Japan and the European Community in the development of medical devices and diagnostics. Spending for research and development in this sector is more than three times the national industrial average. Medical devices and diagnostics have consistently had a robust, positive trade balance, one of the few industrial sectors about which that claim can be made.

Two, if current trends continue, the United States will lag behind both Japan and the European Community in the development of devices and diagnostics by the year 2000.

The favorable trends for Japan and Europe include more Government subsidization of research and development, the availability of less expensive capital and the streamlining of regulatory processes, exemplified by the activities in the European Community expected to be concluded in 1992.

The commerce study concludes if foreign firms develop products based on emerging technologies faster and more effectively than U.S. companies, then the price, performance, and quality of foreign products may surpass U.S. offerings.

In contrast, comparative success by U.S. firms in bringing emerging technologies to market will stimulate more and better quality jobs, increase exports, reduce imports, and contribute directly to material wealth. Not only will such success improve the U.S. civilian industrial base, but it will foster improved national security directly through dual-use technologies and indirectly by advancing the country's economic strength.

We hope the subcommittee keeps those concerns in mind as it develops legislation.

Mr. Allen and I will now be glad to answer any questions.

Mr. WAXMAN. Thank you very much, Mr. Magazine.

Mr. Ferguson.

STATEMENT OF STEPHEN L. FERGUSON

Mr. FERGUSON. Thank you very much, Mr. Chairman. I appreciate the opportunity to appear before you.

My name is Stephen L. Ferguson. I am counsel to the Cook Group Inc., and I am president of CFC, Inc., one of its subsidiaries.

Cook has been in the business of manufacturing medical devices, particularly those used in interventional and diagnostic medicine since 1963. We take pride in having had an important part in many exciting technological changes over the last three decades. We are especially gratified that of the nine devices characterized by the FDA as "breakthrough devices" and approved in 1989, two were developed by Cook.

In our day-to-day business, we manufacture over 4,000 different devices which can be purchased in over 80,000 combinations for diagnosis and treatment of disease. Over 60 million units are shipped each year. Each device is carefully manufactured and inspected. Our incident rate of untoward effect is 0.000007—seven in 1 million.

When considering what products to develop, we try to evaluate the risk and benefit of the devices when compared with alternative patient treatment. Most of our advances come one step at a time.

Revolutionary medical advances are very, very rare; the majority of improvements in medical devices come from a slow evolution. Even our two products cited by the FDA in 1989 as "revolutionary" were evaluated, developed and produced on historical information generally known to physicians and surgeons skilled in diagnostic and interventional procedures.

We appreciate the opportunity to state our views on the important legislation to revise the medical device amendment of 1976. This legislation is of obvious importance to us as a manufacturer, but even more important to American patients who are depending on Congress to enact a law which will ensure that the best available medical treatment is available at the earliest possible moment.

Mr. Chairman, we believe the FDA should be given the authority to waive requirements of the premarket approval process in instances where the necessary information is already available and the required studies would be redundant. The law should not become involved in protecting any company from competition.

The approval process should never be used to reprove what is already known simply because a manufacturer, who happened to be first through the regulatory process, does not want others to use information already gathered. The time of our Nation's doctors and hospitals, our Nation's scientists and laboratories, our Nation's universities, and the lives of experimental animals, should not be used to reprove what has been proven and known. The limited time available to FDA personnel should not be wasted in reviewing millions of pages of reports and studies on what has already been proven. This is a useless waste of time and money.

FDA staff time is a precious commodity. Why should this staff be required to monitor procedures or materials which have already

been proven clinically safe? Why should the FDA waste its valuable time in rereading data which has been previously submitted? Why should the FDA be placed in a position where it must say "we don't know" when it already has previous documentation relative to the integrity of a procedure, a material, or a new device?

No other industry has been required to prove what is already known. This requirement squanders billions of dollars and untold human resources which could be used for patient care.

It is unfortunate that some manufacturers have viewed regulation as a way to protect themselves from their competitors. If everyone must expend several years' effort in the regulatory process, the thinking goes, the first company on the market will be assured protection from competition. This is in addition to the protection a company receives under the patent laws and the patent term extensions provided to compensate for time spent in the approval process. This concept has become known as the "regulatory patent," and we urge Congress to eliminate it.

Frankly, Mr. Chairman, this strikes us as ridiculous and tragic. The only legitimate concern of FDA should be the patient. If a device can contribute to better health care and FDA knows it, the device should be approved for marketing.

Let me provide an example, Mr. Chairman. One of the breakthrough devices approved by the FDA last year was a device developed by our company which uses heat to treat malignant brain tumors. If another manufacturer comes up with a variant of our device or even an exact duplicate of our device, and if the knowledge gained by FDA through the research we performed makes it possible for FDA to eliminate reproving some of the requirements for premarket approval, so be it. If the FDA knows it is a good device, the device should go to market for the benefit of the public.

If the other manufacturer infringes our patents, that is a problem for us to solve in court with patent law. And I assure you, Mr. Chairman, the medical device industry has proven that it will pursue its remedies with vigor. There has been a revolution in patent law.

In addition to providing for patent restoration for those of us who must go through the regulatory process, Congress established the Court of Appeals for the Federal Circuit. This court has revitalized patent law. While patents had fallen into disfavor in some courts in the 1960's and 1970's, they are now being upheld.

The medical device industry is now seeing injunctive relief regularly and promptly. According to Business Week, over 6,000 intellectual property suits were filed in 1988, 60 percent more than in 1980.

In the field of medical devices, the number of patents issued has climbed from 781 in 1979 to 2,667 in 1989. These are records of the U.S. Patent Office. These increases are a result of a new awareness in the business community of the value of patents, thanks to congressional action. In short, we have a robust, effective system to protect intellectual property.

Mr. Chairman, we respectfully urge the committee to provide for a PMA waiver provision in the legislation. The new law should permit FDA to tailor the PMA process so the essential health

issues are dealt with efficiently and effectively, and so redundant research is avoided.

[Testimony resumes on p. 204.]

[The prepared statement of Mr. Ferguson follows:]

TESTIMONY OF STEPHEN L. FERGUSON
ON BEHALF OF
THE COOK GROUP INCORPORATED

Mr. Chairman, my name is Stephen L. Ferguson. I am counsel to the Cook Group Incorporated, and I am president of CFC, Inc., one of its subsidiaries. Cook has been in the business of manufacturing medical devices, particularly those used in interventional and diagnostic medicine since 1963. We take pride in having had an important part in many exciting technological changes over the last three decades. We are especially gratified that of the nine devices characterized by the FDA as "breakthrough devices" and approved in 1989, two were developed by Cook. In our day-to-day business we manufacture over 4,000 different devices which can be purchased in over 80,000 combinations for diagnosis and treatment of disease. Over 60 million units are shipped each year. Each device is carefully manufactured and inspected. The incident rate of untoward effect is 0.000007 (seven in one million).

When considering what products to develop, we try to evaluate the risk and benefit of the devices when compared with alternative patient treatment. Most of our advances come one step at a time. Revolutionary medical advances are very, very rare; the majority of improvements in medical devices come from a slow evolution. Even our two products cited by the FDA in 1989 as "revolutionary" were evaluated, developed and produced on historical information generally known to physicians and surgeons skilled in diagnostic and interventional procedures.

We appreciate the opportunity to state our views on the important legislation to revise the Medical Device Amendment of 1976. This legislation is of obvious importance to us as a manufacturer but even more important to American patients who are depending on Congress to enact a law which will ensure that the best medical treatment is available at the earliest possible moment to improve quality of life or to extend life.

Mr. Chairman, the Subcommittee is now considering H.R. 3095. I will spell out a few principles that we at Cook think are important for Congress to consider as it enacts a new medical device bill.

I. "SAFE AND EFFECTIVE"

It is important for Congress to recognize that there is no device which is 100 percent "safe and effective." We should not kid ourselves--risk will always be a factor to be considered. The use of a modified or new device must be weighed against all other known forms of treatment; the risk/benefit analysis must be the keystone to the approval process. Risk/benefit analysis can avoid costly and time-consuming delays which are now built into the present law. Congress should instruct the FDA to analyze the risks and benefits of medical devices and alternative forms of treatment and approve the devices for marketing based upon this analysis. We believe Congress should clarify that risk/benefit

analysis is indeed the key to device approval to avoid the confusion that arises from the words "safe and effective."

II. THE PROBLEMS OF SCALE UP

Premarket testing, including clinical trials, has significant limitations. During clinical trials, a few of the very best trained physicians in the country evaluate a device, which is usually custom made by skilled employees under the supervision of engineers in a manufacturer's R&D department. Relatively few patients are used in the trials. The trials take place at the best medical centers. From experience, we know that most design flaws or user related complications do not show up in this context. On the contrary, untoward effects normally occur during early production and usage. The device is mass produced rather than custom made. It becomes available to thousands of physicians who do not have experience in its use, and those physicians treat a large population of patients, not just 50, 100 or 200.

We can expand requirements for premarket approval, but we will never duplicate the factors which come into play when a device is manufactured and marketed. For this reason, we believe that the greatest contribution Congress can make in protecting the public from faulty devices is to emphasize post approval surveillance and GMP (good manufacturing practice) enforcement.

Inspection with attention to incident reports during the first year of use will do much to eliminate a majority of device failures. In contrast, expansion of requirements for premarket approval will tie up resources of the FDA, manufacturers, researchers, laboratories, and the medical profession, will delay device availability to the patient, and will fail in directing attention to the scale up period. The system of GMP is in place, but more enforcement and inspections are needed.

III. THE EVOLUTIONARY NATURE OF DEVELOPMENT OF DEVICES

Mr. Chairman, we think it is important to recognize that the development of new medical devices is largely an evolutionary rather than a revolutionary process. Progress usually comes through one small modification at a time. A doctor may be using a device and realize that a minor modification will make it work better. He makes a suggestion, and the manufacturer comes out with a slightly different device. Later a doctor realizes that with another minor change the device could be helpful for a slightly different application. And so it goes.

The critical point is that much information and experience is available for approval of these evolutionary devices. The manufacturer should not have to go through a PMA (pre-market approval) process each time these new devices come to the market. A streamlined process for approval such as that contained in

section 510(k) is essential to ensure that the progress we make a step at a time does not come to a profound halt. Allowing prompt approval of devices which are similar to those already on the market does not constitute a loophole which jeopardizes the public safety. The information gained from the history of the predicate device, which has been mass produced by manufacturers, which is familiar to a large number of physicians, and which has been used successfully on behalf of thousands of patients, provides a much greater assurance than any clinical trial ever can. If the process is amended so that new devices are compared with those currently marketed, rather than those marketed prior to 1976, the concept of 510(k) is upheld and should remain.

IV. THE PMA WAIVER

Mr. Chairman, we believe the FDA should be given the authority to waive requirements of the premarket approval process in instances where the necessary information is already available and the required studies would be redundant. The law should not become involved in protecting any company from competition.

The approval process should never be used to reprove what is already known simply because a manufacturer, who happened to be first through the regulatory process, does not want others to use information already gathered. The time of our nation's doctors and hospitals, our nation's scientists and laboratories, our

nation's universities, and the lives of experimental animals, should not be used to reprove what has been proven and known. The limited time available to FDA personnel should not be wasted in reviewing millions of pages of reports and studies on what has already been proven. This is a useless waste of time and money.

FDA staff time is a precious commodity. Why should this staff be required to monitor procedures or materials which have already been proven clinically safe? Why should the FDA waste its valuable time in rereading data which has been previously submitted? Why should the FDA be placed in a position where it must say "we don't know" when it already has previous documentation relative to the integrity of a procedure, a material, or a new device? No other industry has been required to prove what is already known. This requirement squanders billions of dollars and untold human resources which could be used for patient care. Regulations should not restrict innovation because one manufacturer believes that others should spend the same amount of money for regulatory verification.

It is unfortunate that some manufacturers have viewed regulation as a way to protect themselves from their competitors. If everyone must expend several years effort in the regulatory process, the thinking goes, the first company on the market will be assured protection from competition. This is in addition to

the protection a company receives under the patent laws and the patent term extensions provided to compensate for time spent in the approval process. This concept has become known as the "regulatory patent," and we urge Congress to eliminate it.

In the context of medical devices, the regulatory patent is created by provisions in the law relating to the PMA process that forbid the FDA from utilizing knowledge gained in prior research in approving other devices. The FDA must pretend it doesn't know what it knows, and require each manufacturer to prove the same principles over and over again even when it is known to the public. If one manufacturer demonstrates through clinical trials that a certain substance is safe for use in devices which dwell in the body, the next manufacturer must prove it again. So must the next and the next and the next. FDA does not have discretion to waive any of the requirements for premarket approval. Even though the FDA knows the substance is safe, it must act as if it knows nothing. The FDA must require manufacturers to waste their research, time, animals and resources to reprove that which is well known, and it must waste its own resources to make sure that the company carries out all the studies and trials correctly.

Frankly, Mr. Chairman, this strikes us as ridiculous and tragic. The only legitimate concern of FDA should be the

patient. If a device can contribute to better health care and FDA knows it, the device should be approved for marketing.

Let me provide an example, Mr. Chairman. One of the breakthrough devices approved by the FDA last year was a device developed by our company which uses heat to treat malignant brain tumors. If another manufacturer comes up with a variant of our device or even an exact duplicate of our device, and if the knowledge gained by FDA through the research we performed makes it possible for FDA to eliminate reproving some of the requirements for premarket approval, so be it. If the FDA knows it's a good device, the device should go to market for the benefit of the public.

If the other manufacturer infringes patents, that is a problem for us to solve in court with patent law. And I assure you, Mr. Chairman, the medical device industry has proven that it will pursue its remedies with vigor. There has been a revolution in patent law. In addition to providing for patent term restoration for those of us who must go through the regulatory process, Congress established the Court of Appeals for the Federal Circuit. This court has revitalized patent law. While patents had fallen into disfavor in some courts in the 1960s and 1970s, they are now being upheld. The medical device industry is now seeing injunctive relief regularly and promptly. According

to Business Week, over 6,000 intellectual property suits were filed in 1988, 60% more than in 1980. In the field of medical devices the number of patents issued has climbed from 781 in 1979 to 2,667 in 1989 (Records of U.S. Patent Office). These increases are a result of a new awareness in the business community of the value of patents, thanks to Congressional action. In short, we have a robust, effective system to protect intellectual property.

Mr. Chairman, we respectfully urge the Committee to provide for a PMA waiver provision in the legislation. The new law should permit FDA to tailor the PMA process so the essential health issues are dealt with efficiently and effectively, and so redundant research is avoided. This provision would assist the FDA and the manufacturer in bringing new technology to the market place in a shorter time. The beneficiary would be the patient. It is important that strong and clear language be included to allow the FDA to eliminate reproving what is already known to all.

V. HUMANITARIAN DEVICE EXEMPTION

Finally, Mr. Chairman, there should be a method for streamlined approval of limited use devices. We call this a "humanitarian device exemption" in a proposal we have submitted to your staff. The exemption need not provide money or special

exclusivity for developing orphan products but rather a simpler, less costly system to get them to a limited market. We believe most manufacturers will develop such devices which fall within their expertise if approval costs are not exorbitant. A humanitarian device exemption would lower those costs.

VI. **CONCLUSION**

Thank you, Mr. Chairman, for inviting us to submit our views. The Committee has a wonderful opportunity to improve the law governing medical devices and in so doing to provide better medical technology more promptly to the patient. We believe that it is important for Congress to recognize the principle that there are no risk free devices, to recognize the problems of scale up to mass production and use, and to understand the evolutionary nature of device development. Further, we think it is important for the new law to eliminate the redundancy of requirements for information, clinical trials, and tests when approving devices. The FDA must be allowed to use information secured previously. We think it is important for the new law to eliminate the regulatory patent, which delays the availability of devices to the patient. The laws should also ease the burdens of those who would like to bring devices to the market which will be used by only a few patients.

We congratulate you and the Committee for your interest in this very important subject. Revising the medical devices law has been a lengthy process, and we are grateful for your stamina and perseverance. We wish you the very best in your deliberations.

Mr. WAXMAN. Thank you very much, Mr. Ferguson.
Mr. Bailey.

STATEMENT OF J. DAN BAILEY

Mr. BAILEY. Mr. Chairman, my name is Dan Bailey. I am president of the Contact Lens Manufacturers Association. With me is Dan Minelli, and I would like to summarize my statement so I can respond to some questions raised this morning.

The CLMA represents approximately 150 manufacturers. Our members are typical of the medical device industry as a whole: Most of us are small to medium-size, privately owned companies.

Contact lenses have been actively marketed in this country since the late 1940's. Our members have established an outstanding safety record. Yet, the smaller contact lens manufacturers have had difficulties under the present law, as you know.

This has been documented over the years in a number of reports issued by the Congressional Office of Technology Assessment and your own Oversight and Investigations Subcommittee and in hearings before this subcommittee.

Some years ago, for example, the OTA concluded that major portions of the medical device amendments have not been implemented by FDA, and some may not be workable. As implemented so far, the regulatory process has posed the greatest problem for small manufacturers of contact lenses.

These have locked the now commonplace RGP daily wear lens into class 3, the highest and most expensive level of regulation.

The daily wear RGP lens is the mainstay of most of our member companies. It is an improved variant of the now obsolete "hard" or PMMA lens. The PMMA lens is still in use and has had a distinguished history of safe and effective use throughout the world. The RGP lens, however, permits oxygen to diffuse directly through the lens to the eye, thus providing greater comfort and cornea health.

Class 3 was not intended for devices like the RGP lens. The law defines a class 3 device as one which is life-supporting or which presents a "potential unreasonable risk of illness or injury." It is not surprising that class 3 accounts for only about 7 percent of all medical devices; examples are heart valves and pacemakers.

The remaining medical devices, some 93 percent of the total, are either in class 1 or class 2. These devices range from some very simple ones, such as tongue depressors, to complex devices such as heart defibrillators, anesthesia machines, medical lasers, artificial hip, knee, shoulder and ankle joints, and hundreds of others.

Paradoxically, the now obsolete PMMA contact lens is also regulated at this level, while the safer and more effective RGP lens remains locked in class 3.

What we are saying to the subcommittee is that genuine class 3 medical devices, devices that actually meet the legal definition, will never receive the attention they deserve so long as relatively innocuous devices are kept in class 3.

CLMA therefore supports this legislation. In particular, CLMA supports the legislation's proposed changes to section 520(*l*) of the act. For reasons already indicated, we believe that these changes

are essential to accomplishing the overall objectives of the legislation.

A former FDA Commissioner described the problem and emphasized the need for corrective legislation:

> A major PMA problem involves transitional devices. By statute, these devices are automatically placed in class 3 instead of going through the classification process. Therefore, these devices require approved premarket approval applications before they may be marketed. If we are to amend this situation this situation, it is difficult to envision a solution other than legislative change.

This is the crux of the problem. The transitional devices have not gone through the regular classification process. This has meant artificially high costs for manufacturers, and it has wasted FDA's efforts on needless reviews.

Few, if any, of the transitional devices now subject to PMA submissions meet the legal definition for a class 3 device. Despite this, the majority of PMA submissions now processed by the FDA are for transitional devices. PMA's and PMA supplements for contact lenses and related products account for approximately 40 percent of the total.

It results in continuous economic pressure on smaller companies and diversion of FDA's resources from genuine public health concerns. The long overdue reclassification of this category of lens would free a large block of FDA's resources for more pressing tasks.

We think that the wastefulness of the current situation is now recognized by the FDA and the Department of HHS as well. In the last Congress, the Senate Labor and Human Resources Committee reported favorably on S. 1808. That medical device legislation was much narrower in scope than the bill being considered today. It was limited to the transitional provisions and was similar in approach to section 4 of H.R. 3095.

In his letter to Senator Kennedy commenting on S. 1808, the Secretary of HHS stated, in part:

> Should these classification proceedings lead to less regulation of some medical devices, FDA resources could be shifted to other activities with higher public health payoff. The bill could make it easier for FDA to "down-classify" some devices that may be inappropriately, and therefore wastefully, regulated as class 3 devices.
>
> Because transitional devices, primarily contact lenses, account for approximately half of all applications for premarket approval received by FDA, this bill does offer the potential for freeing some Agency resources for the review of applications involving newly emerging technologies and devices that pose significant potential public health risks.

I would like to briefly respond to the points made by Mr. Scheuer this morning.

Mr. WAXMAN. Mr. Bailey, your time has expired, but it is in the record, and it will be in the transcript to be shared by our colleagues. Thank you.

[The prepared statement of Mr. Bailey follows:]

Statement of J. Dan Bailey
President, Contact Lens Manufacturers Association
before the
Subcommittee on Health and Environment
Committee on Energy and Commerce
U. S. House of Representatives

July 17, 1990

Mr. Chairman, my name is J. Dan Bailey. I am President of the Contact Lens Manufacturers Association (CLMA). We appreciate the opportunity to present our views on this important legislation.

The CLMA represents approximately 150 manufacturers. The Regular Members of the association are engaged in the manufacture of contact lenses. Associate Members are manufacturers of related products, such as lens blanks and optical lathes. Our members are typical of the medical device industry as a whole; most of us are small to medium-size privately owned companies.

Contact lenses have been actively marketed in this country since the late 40's. Our members have established an outstanding safety record. One of the reasons is that we deal directly with the eye care practitioner. The contact lenses we manufacture are subjected to careful inspection by us and by the practitioner before they are fitted to his or her patients. Any contact lens manufacturer who is unable or unwilling to meet the highest standards does not belong in this market, and will not survive in it for long.

Yet the smaller contact lens manufacturers have had difficulties under the present law, as you know. This has been documented over the years in a number of reports issued by the Congressional Office of Technology Assessment (OTA) and your own Oversight and Investigations Subcommittee and in hearings before this Subcommittee. Some years ago, for example, the OTA concluded that:

> [M]ajor portions of the Medical Device Amendments have not been implemented by FDA and some may not be workable. As implemented so far, the regulatory process has posed the greatest problem for small manufacturers of contact lenses.[1]

We agree with that statement. I want to make clear that our problems with the present law have not related to safety issues or the quality of our products. The problem has been that portions of the present law have been costly barriers to competition. Specifically, the so-called "transitional" provisions. These have locked the now commonplace RGP daily wear lens into class III, the highest and most expensive level of regulation.

The daily wear RGP lens is the mainstay of most of our member companies. It is an improved variant of the now obsolete "hard" or PMMA lens. The PMMA lens is still in use and has had a distinguished history of safe and effective use throughout the

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[1] "Federal Policies and the Medical Device Industry;" October 1984.

world. The RGP lens, however, permits oxygen to diffuse directly through the lens to the eye, thus providing greater comfort and corneal health.

Class III was not intended for devices like the RGP lens. The law defines a class III device as one which is life supporting or which presents a "potential unreasonable risk of illness or injury." It is not surprising that class III accounts for only about seven percent of all medical devices; examples are heart valves and pacemakers.

The remaining medical devices, some 93 percent of the total, are either in class I or class II. These devices range from some very simple ones, such as tongue depressors, to complex devices such as heart defibrillators, anesthesia machines, medical lasers (including the Nd:YAG laser used for posterior capsulotomy), artificial hip, knee, shoulder and ankle joints, and hundreds of others.[2] Paradoxically, the now obsolete PMMA contact lens is also regulated at this level while the safer and more effective RGP lens remains locked in class III for reasons which I will explain.[3]

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[2] These can be found listed in FDA regulations; 21 CFR Part 800.

[3] In January of 1982, FDA proposed to place PMMA contact lenses in class II (47 Fed. Reg. 3694) - that proposal is still pending, after more than eight years.

We are not saying that classes I and II are inadequate for regulation of the many diverse devices assigned to them. On the contrary, the FDA's authority to regulate devices in those classes is extensive. All devices, as you know, are subject to the "general controls" of the medical device law. This collective term includes seven complex sections of the law and over 100 pages of small-print FDA regulations. H.R. 3095 would add the concept of "special controls" to regulation of class II devices. In our opinion, the general controls, as they now exist, are more than adequate for regulation of the RGP contact lens.

What we are saying to the Subcommittee is that genuine class III medical devices - devices that actually meet the legal definition - will never receive the attention they deserve so long as relatively innocuous devices are kept in class III.[4]

CLMA therefore supports this legislation. In particular, CLMA supports the legislation's proposed changes to Section 520(l) of the Act. For reasons already indicated, we believe that these changes are essential to accomplishing the overall objectives of the legislation.

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[4] In a 1985 report, The Health Industry Manufacturers Association concluded that the FDA's failure to reclassify RGP lenses and other devices "has contributed to delays in the product approval process and will continue to do so until changed." (Report and Recommendations of the HIMA Device and Diagnostic Product Approval Task Force (October 1985, p. 25).

Section 520(l) contains the so-called - and badly misnamed - transitional provisions. These have remained in place for 14 years and have resulted in a considerable waste of FDA's resources throughout that time. This has diminished FDA's ability to review premarket approval applications (PMA's) for non-"transitional" devices. A former FDA Commissioner described the problem and emphasized the need for corrective legislation:

> [A] major PMA problem involves transitional devices . . . . By statute, these devices are automatically placed in class III instead of going through the classification process. Therefore, these devices . . . require approved premarket approval applications before they may be marketed. . . . If we are to amend this situation, it is difficult to envision a solution other than legislative change.[5]

That is the crux of the problem. The transitional devices have not gone through the regular classification process. This has meant artificially high costs for manufacturers, and it has wasted FDA's efforts on needless reviews.

Few, if any, of the transitional devices now subject to PMA submissions meet the legal definition for a class III device. Despite this, the majority of PMA submissions now processed by the FDA are for transitional devices. PMA's and PMA Supplements for contact lenses and related products account for approximately 40 percent of the total.

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[5] FDA Commissioner Frank Young, Speech to Health Industry Manufacturers Association, March 18, 1985.

The PMA process for the RGP daily wear lens has evolved into a slow and expensive ritual. It results in continuous economic pressure on smaller companies and diversion of FDA's resources from genuine public health concerns. The long overdue reclassification of this category of lens would free a large block of FDA's resources for more pressing tasks.

When the FDA found that it could not reclassify RGP lenses under the present wording of the law, it stated:

> [R]eclassification of rigid gas permeable lenses would have resulted in increased competition, decreased costs, and an increase in employment and also would have allowed small contact lens firms to compete in the world market.[6]

We are encouraged to believe that the wastefulness of the current situation is now recognized by the FDA and the Department of HHS as well. In the last Congress the Senate Labor and Human Resources Committee reported favorably on S. 1808. That medical device legislation was much narrower in scope than the bill being considered today. It was limited to the transitional provisions and was similar in approach to Section 4 of H.R. 3095.

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[6] 48 Federal Register 56798.

In his letter to Senator Kennedy commenting on S. 1808, the Secretary of HHS stated, in part:

> [S]hould these classification proceedings lead to less regulation of some medical devices, FDA resources could be shifted to other activities with higher public health payoff. . . . [The bill] could make it easier for FDA to "down-classify" some devices that may be inappropriately, and therefore wastefully, regulated as class III devices.
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> * * *
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> [B]ecause transitional devices, primarily contact lenses, account for approximately half of all applications for premarket approval received by FDA, this bill does offer the potential for freeing some agency resources for the review of applications involving newly emerging technologies and devices that pose significant potential public health risks, thus permitting faster product reviews for devices with potentially greater public health benefit.[7]

Attempts to use the FDA as a regulatory barrier to competition are nothing new. Such attempts are increasingly objectionable as needs for public health increase and agency resources remain level or decrease.

We have no specific comment to offer regarding the adverse experience reporting requirements contained in Section 2 of the bill. In our opinion, such incidents have not and will not occur with respect to the contact lenses we manufacture today or those likely to appear in the future.

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[7] Letter from HHS Secretary Otis R. Bowen, M.D. to Hon. Edward M. Kennedy; September 29, 1988.

The bill would also define substantial equivalence for purposes of sections 513, 515 and 520 of the Act. We interpret this definition to be consistent with present FDA reviewing standards. These were specified in the agency's June 1986 guidance document. We have one recommendation to make with respect to this definition.

Specifically, the bill uses the term "technological characteristics" as one of the criteria for evaluating substantial equivalence. A device would be deemed to have different technological characteristics is there is "a significant change in the materials, design, energy source, or other features from those of the device to which it is being compared."

We recommend that the words "significant change" be more clearly equated to those changes affecting the safety or effectiveness of the device. This would be consistent with present FDA regulations governing significant changes which require the submission of supplemental PMA's (21 CFR 814.39).

In closing, Mr. Chairman, I want to again emphasize our conviction that FDA's processes should not be a competitive battleground in which "haves" and "have not's" battle over the retention of obsolete regulatory barriers. This use of the FDA injures not only competition but the public health as well. We hope that the Subcommittee will move forward with this badly needed legislation and will make clear its intent that the non-class III devices must be cleared out of class III so that those devices which remain in class III can get the attention they deserve.

Thank you again for the opportunity to present these views.

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Mr. WAXMAN. Mr. Britain.

STATEMENT OF ROBERT G. BRITAIN

Mr. BRITAIN. Thank you, Mr. Chairman, and good afternoon also to the subcommittee members.

First of all, I would like to introduce Bill Gerber on my right. Bill is manager of Industry Relations at Picker International; they make diagnostic imaging devices. He is also chairman of our NEMA's Government Relations Committee.

I would like to inform the—or remind some of the committee that this particular industry is just a segment of the medical device industry. We do not represent the total industry. Our manufacturers make diagnostic imaging devices and some radiation therapy devices.

I would also like to say this particular industry has, for 22 years, been regulated by the Radiation Control for Health and Safety Act that was enacted in 1968. This industry has been subject to civil monetary penalties. It has been subject to Federal standards.

For example, two of them are the x-ray standard and the Federal laser standard. It has been subject to reporting, initial reports, model change reports and annual reports, just as a little background to where we are coming from.

Mr. Chairman, I would like to summarize our written statement by focusing on two issues which we think are most important. The first is substantial equivalence, and the second is international competitiveness.

The substantial equivalence program, we believe, is one of the most important programs for medical devices in FDA. As you have heard, it is the regulatory route to the marketplace for over 90 percent of current medical devices, and I think the correct figure is closer to 94 percent. It is also a resource-intensive program, both for industry and FDA.

In fiscal year 1989, a little less than 100 FTE's were expended by FDA reviewing section 510(k)'s. In that same year, FDA received about 7,000 section 510(k)'s. Any increase in regulatory requirements to the FDA to the section 510(k) program will mean substantial strain on those in FDA reviewing those section 510(k)'s. This strain, of course, will result in long delays in making section 510(k) decisions.

We are extremely concerned about the provision in H.R. 3095 which apparently calls for the elimination of the section 510(k) route to market for medical devices. Medical devices—at least diagnostic imaging devices, tend to be evolutionary. The medical device of today is more like—likely the sum of many incremental changes made over a period of years.

The section 510(k) process allows for an effective review of these incremental changes and provides the public with continued access to steadily improving devices.

The section 510(k) program has been relatively successful, because FDA has maintained some flexibility in its implementation. The current language of H.R. 3095 could jeopardize this flexibility.

For example, by mandating that the Secretary, by order, engage in determinations of substantial equivalence, there will be institut-

ed, in effect, another layer of product review by FDA officials, including, for example, FDA counsel.

Flexibility of the section 510(k) market notification process will evaporate and review times will substantially increase without tangible benefit to the public health and safety, and that is what we are concerned about, without the tangible benefit added.

Accordingly, we would suggest existing FDA practice with respect to the review of section 510(k) submissions, and would delete those portions of the—we would suggest, codefine existing practice would suggest deleting those portions of H.R. 3095 which go beyond the current FDA practice.

We also—NEMA also remains opposed to the requirement that FDA issue a detailed summary of safety and effectiveness data each time a device is found to be substantially equivalent to a predicate device. This would result in a serious impact on FDA resources, and it is not clear to us that there would be any concomitant improvement in the public health.

We would therefore suggest deleting this requirement for H.R. 3095. If that bell was for me, Mr. Chairman, I just have 30 seconds.

Mr. WAXMAN. Thirty seconds.

Mr. BRITAIN. One area not addressed by the bill, which we believe should be a key element of medical device legislation, is international competitiveness, and the issue of global competitiveness in assuming increased importance for American industry as the European Community reaches its goal of achieving a unified internal market by 1992.

I think the bottom line is, Mr. Chairman, we have some proposed language attached with our comments, which would place an office in FDA that is focused on this particular area of international competitiveness.

Thank you.

[Testimony resumes on p. 226.]

[The prepared statement of Mr. Britain follows:]

STATEMENT OF THE DIAGNOSTIC IMAGING AND THERAPY SYSTEMS DIVISION OF THE NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

Good morning, distinguished Chairman, and Subcommittee members. I am Robert G. Britain, Manager of NEMA's Diagnostic Imaging and Therapy Systems Division. Joining me today is William J. Gerber, Manager of Industry Relations at Picker International, a manufacturer of diagnostic imaging equipment located in Cleveland, Ohio, and Chairman of the Division's Government Relations Committee.

The Diagnostic Imaging and Therapy Systems Division of the National Electrical Manufacturers Association is pleased to provide the members of the Subcommittee on Health and Environment with a statement of its views on H.R. 3095, the Safe Medical Devices Act. NEMA, the National Electrical Manufacturers Association, is the nation's leading trade association representing electrical manufacturers. NEMA's Diagnostic Imaging and Therapy Systems Division represents more than 95% of U.S. manufacturers of x-ray imaging, computed tomography, nuclear imaging, radiation therapy, diagnostic ultrasound, and magnetic resonance imaging equipment. In addition, NEMA represents manufacturers of extracorporeal shockwave lithotripters and picture archiving and communications systems. We at NEMA look forward to working with Subcommittee staff in the development of legislation which will provide the public with continued assurance that medical devices are safe and effective.

Over the past year, the Subcommittee on Health and Environment, in concert with the Subcommittee on Oversight and Investigations, has held a series of hearings focusing on FDA's existing MDR system. In an effort to improve FDA tracking of device malfunctions, H.R. 3095 envisions an elaborate user reporting scheme whereby hospitals and medical facilities would be required to file reports with both FDA and device manufacturers for every device malfunction which has caused or contributed to life-threatening injury or death to the patient. In addition, H.R. 3095 requires user reporting when a user facility becomes aware of information which reasonably suggests that a medical device is likely to malfunction, and that the resulting malfunction is likely to result in death or life-threatening injury to the patient. Finally, H.R. 3095 requires health care distributors to engage in the filing of MDR reports. Manufacturers, distributors, and importers of medical devices would be required to submit annual reports to DHHS certifying why they did or did not file MDR reports during the preceding year.

NEMA believes that certain user reporting requirements delineated in H.R. 3095 are unnecessarily burdensome, and will only hamper the FDA in its efforts to identify those device malfunctions which are most likely to result in serious harm to patients.

The purpose of user reporting is to identify serious malfunctions early in the life cycle of a medical device. A well-designed user reporting system should function as an early warning system, and should assist the FDA in identifying those devices which are worthy of further scrutiny. Accordingly, user reporting should focus only on those device malfunctions which have resulted or have the potential to result in life-threatening injury or death. User reporting requirements which ask for the prediction of device malfunctions are impractical and will serve only to prevent the FDA from concentrating its resources on those malfunctions which, if left unchecked, are most likely to harm patients.

As the work of the Subcommittee over the past twelve months has demonstrated, the FDA, despite good faith efforts, presently lacks the ability to manage the existing volume of MDR reports. For example, the GAO, in a February 1989 report to the Subcommittee Chairman, found that close to one third of the reports submitted under the MDR system have not been fully processed to closure, including more than 10,000 malfunction reports.

By imposing additional user reporting requirements, H.R. 3095 merely exacerbates these problems by increasing the resource burden on an already overburdened agency. Clearly, what is needed is a targeted user reporting system so that FDA is able to

use the information contained in user reports wisely. Additional reporting requirements should focus only on those device malfunctions which have resulted or could result in life-threatening injury or death. This targeted reporting system will then provide the FDA with the information necessary to address real device malfunctions instead of wasting limited resources on hypothetically possible malfunctions and injuries.

Accordingly, NEMA would delete language contained in section 519(b)(1)(B) which pertains to user reporting of potential device malfunctions, as well as the additional reporting requirements specified by sections 519(b)(1)(C), and 519(c) from H.R. 3095. NEMA would also modify section 519(a)(3) of the proposed legislation to require distributor reporting only of device malfunctions that have resulted or could result in life threatening injury or death.

Furthermore, NEMA believes that section 519(d)(1) of H.R. 3095, which requires manufacturer reporting of field modifications and repairs, imposes an unnecessary burden on both the FDA and manufacturers for no measurable improvement in public health. There seems little purpose in reporting and reviewing device modifications which have already been implemented. Since reports of field modifications and repairs appear in the FDA Enforcement Report, there is the very real prospect of unduly alarming users over equipment modifications long since adopted.

In addition, regulations promulgated at 21 CFR 820.198 require manufacturers to investigate any complaint pertaining to injury, death or product safety. A written record of this investigation is required to be maintained and be available to FDA officials for review. It is difficult to conceive of an investigative report which fails to include corrective action measures taken by the manufacturer. Therefore, the information required by section 519(d)(1) is readily available for review by FDA officials. Indiscriminate reporting of all field modifications will burden FDA without any measurable improvement in public health. Accordingly, NEMA maintains that section 519(d)(1) of H.R. 3095 is of no benefit to the public safety and health, and merely imposes a duplicate reporting requirement on manufacturers.

Substantial Equivalence

NEMA remains strongly opposed to the provision in H.R. 3095 which calls for the elimination of the section 510(k) route to market for manufacturers of medical devices. Medical devices, at least diagnostic imaging devices, tend to be evolutionary. The medical device of today is more than likely the sum of many incremental changes made over a period of years. The 510(k) process allows for an effective review of these incremental changes and provides the public with continued access to steadily improving devices with little or no risk to the public health.

Over the years, the 510(k) product review process has evolved in recognition of the incremental evolution of medical devices. In a practical sense, this means that the type of information which FDA requires in conjunction with a 510(k) submission varies significantly in accordance with the type of medical device. For some types of class I and class II devices, a comparatively simple premarket notification may be all that is required. For more complex types of medical devices, the agency requires additional supporting documentation. Thus, section 510(k) of the current statute has provided the FDA with an important tool for varying the degree of scrutiny accorded to new medical devices prior to market. We at NEMA feel that it is important that this flexibility be retained.

The current language of H.R. 3095 fails to retain this flexibility. By mandating that the Secretary by order engage in determinations of substantial equivalence, there will be instituted, in effect, another layer of product review by FDA officials including FDA counsel. The flexibility of the 510(k) premarket notification process will evaporate and review times will substantially increase without any tangible benefit to the public health and safety. Accordingly, NEMA would codify existing FDA practice with respect to the review of 510(k) submissions, and would delete those portions of section 520(m) which go beyond current FDA practice.

NEMA also remains opposed to the requirement that FDA issue a detailed summary of safety and effectiveness data each time a device is found to be substantially equivalent to a predicate device. This would result in a serious impact on FDA resources, and it is not clear that there would be any concomitant improvement in the public health. NEMA would, therefore, delete this requirement from section 520(m) of the proposed legislation. NEMA would retain current law requirements for the submission of safety and effectiveness data in conjunction with PMA's, product development protocols, and exemptions from Section 516 of the Federal Food, Drug, and Cosmetic Act.

Civil Monetary Penalties and Expanded Recall Authority

With respect to draft language prepared by the Subcommittee Chairman which would give the FDA expanded recall authority, as well as the authority to impose civil monetary penalties upon firms in violation of Chapter 5 of the Federal Food, Drug, and Cosmetic Act, NEMA is still in the process of evaluating this language and thus our Board of Directors has not yet adopted a formal statement of policy. However, an initial review of this draft language suggests that the scope of these two provisions may be unduly broad.

I am particularly concerned about the provision which would give the Secretary the authority to assess civil monetary penalties. For example, further clarification is needed as to the severity of an infraction which would warrant the issuance of a civil monetary penalty. In addition, it is unclear as to the extent to which the Secretary's authority to assess penalties would be retroactive. We at NEMA feel that clarification of these issues is essential as the Subcommittee proceeds in its deliberations.

Performance Standards for the Regulation of Class II Devices

NEMA believes that H.R. 3095 takes an important step forward by acknowledging the inability of the current regulatory system to arrive at adequate performance standards for Class II devices. It is therefore important to provide the Secretary with the authority to use "special controls" such as voluntary performance standards or guidelines to ensure the safety of class II devices. NEMA believes that H.R. 3095 provides the FDA with the flexibility to arrive at the type of control best suited to each given class II device, and feels that it is important that this section of H.R. 3095 be retained.

International Competitiveness

One area not addressed by H.R. 3095 which NEMA maintains should be a key element of medical device legislation is international competitiveness. The issue of global competitiveness is assuming increased importance for American industry as the European community approaches its goal of achieving a unified internal market by 1992. In order to ensure that U.S. firms are able to compete in today's rapidly changing technological environment, it is crucial that the FDA be granted the authority to enter into agreements with foreign governments to provide for the mutual recognition of product review process and other regulations governing the export and manufacture of medical devices. Attached as Exhibit A is NEMA language which would grant the FDA the authority to carry out this important task, thus ensuring the ability of U.S. firms to compete globally in the twenty-first century.

We at NEMA wish to thank the Subcommittee for this opportunity to present our views on medical device legislation. We look forward to working with members of the Subcommittee in the development of legislation which will ensure continued public access to safe and effective medical devices.

EXHIBIT A

PROPOSED NEMA PROVISION

1) OFFICE OF INTERNATIONAL COMPETITIVENESS

SUMMARY:

The issue of global competitiveness is assuming increased importance for American industry as the European community approaches its goal of achieving a unified internal market by 1992. In order to ensure that U.S. firms are able to compete in today's rapidly changing technological environment, it is crucial that the Department of Health and Human Services be granted the authority to enter into agreements with foreign governments to provide for the mutual recognition of product standards and other regulations governing the export and manufadture of medical devices. The NEMA provision would grant the Secretary the authority to carry out this important task, thus ensuring the ability of U.S. firms to compete globally in the twenty-first century.

PROVISION:

SEC.( ) -- ESTABLISHMENT OF THE OFFICE OF INTERNATIONAL COMPETITIVENESS

There shall be added to 21 U.S.C. 381 a new subsection (e) as follows:

(e) The Secretary shall have the authority to enter into agreements with foreign governments such that devices manufactured in accordance with the rules and regulations for device manufacture authorized by 21 U.S.C. section 321 et. seq. shall be deemed suitable by foreign governments for commercial distribution. Similarly, the Secretary shall have the authority to approve devices manufactured abroad in accordance with the rules and regulations of foreign governments for introduction into interstate commerce in the United States.

(1) In entering into such agreements, the Secretary shall encourage the mutual recognition of good manufacturing practice regulations promulgated at 21 U.S.C. section 360j (f), as well as the mutual recognition of other rules, regulations, and testing protocols as deemed appropriate.

(2) In approving devices manufactured abroad for introduction into interstate commerce in the United States, the Secretary shall consider only those devices manufactured in accordance with rules and regulations that provide a reasonable assurance of safety and effectiveness.

(A) The Secretary is to establish an Office of International Competitiveness which would plan and initiate programs for the recognition of devices as set forth in 21 U.S.C. 381(e) above.

(B) The Secretary shall have the authority to issue regulations pursuant to the authority granted in 21 U.S.C. 381(e) above.

(C) There shall be authorized to be appropriated for fiscal years 1990, 1991, and 1992, the sums of $_____, $_____, and $_____, repsectively for the Secretary to initiate the activities described at 21 U.S.C. 381(e) above.

(D) The Secretary shall report to the Congress annually on the activities of the Office of International Competitiveness.

Mr. WAXMAN. Thank you very much, Mr. Britain.

Let me start off the questions. Mr. Magazine, while you say HIMA wants to conserve FDA resources, you want FDA to continue performing redundant, unnecessary tests as part of the PMA process. FDA disagrees with you. Mr. Ferguson disagrees with you.

Why should your members be required to prove what is already known? Aren't you persuaded by Mr. Benson's request for discretion on this issue?

Mr. MAGAZINE. I am going to ask Mr. Allen to help me with this.

Mr. ALLEN. During the course of developing a medical device that has to go through PMA process, a manufacturer may have to expend millions of dollars, and in the course of that development, they develop a cope of proprietary information. The incentive to prepare that type of product and to develop that information is removed completely, if after the course of developing that product, anyone can come in and take advantage of that information that has been obtained, after lots of financial investment and lengthy development.

Mr. WAXMAN. Mr. Ferguson said the patent laws would protect that, that FDA shouldn't be involved in the patent laws. Do you disagree with that?

Mr. ALLEN. I think the application of patent law in the device area is very unusual. The nature of products in the medical device area is that of rapid development, with incremental changes, and our manufacturers do not believe the patent law provides the adequate protection.

Mr. WAXMAN. Mr. Ferguson, you endorsed a procedure for expediting PMA approvals. You heard, however, because medical devices are harder to patent, they deserve special protection. Do you believe that is true?

Mr. FERGUSON. No, I don't, and I think in fact, from recent litigation, the Lilly Electronics litigation, which became famous, is a good example, but within the last year, we have had four or five infringement suits ourselves over minor deviations.

There has been a rapid change that all of us in the manufacturing are going to have to pay attention to, but I don't think that is any longer true.

Mr. WAXMAN. Mr. Magazine, would you briefly explain the impact of changes in the European Community on U.S. medical devices? Perhaps Mr. Allen would—what are the Europeans doing about preproduction quality controls, as well?

Mr. ALLEN. They are looking at the same type of guidance documents that are coming out of FDA, but I think that like the FDA, they are not ossifying those by incorporating them into statutory language or regulatory language, but are using them as guidelines at this point.

Mr. WAXMAN. Mr. Britain, do you want to respond?

Mr. BRITAIN. The European Community is establishing a testing and certification program for medical devices which would incorporate a series of certification procedures, one of which probably will be the ISO 9000, which will include design, but there will be alternatives.

There will be an alternative, like for example GMP in the United States. That will be an alternative to certification in the

European Community. It is—right now, it is a mixed bag, and remember, it is not in place yet. So, we are looking at a moving target.

Mr. WAXMAN. Mr. Whittaker.

Mr. WHITTAKER. Mr. Ferguson, does the swiftness with which medical devices are incrementally improved make patent protection irrelevant for most medical devices?

Mr. FERGUSON. No, it doesn't.

Mr. WHITTAKER. Mr. Bailey, you referenced that you wish to respond to some of the comments made at the beginning of this testimony, and your time did not allow. I would like to offer you some opportunity to make those responses now.

Mr. BAILEY. Thank you, Dr. Whittaker.

I just wanted to mention that there was a reference this morning of the 3½ year FDA proceeding, followed by court action. I wanted to point out CLMA filed reclassification in March 1981. It was submitted to FDA Ophthalmologic in April 1981 and approved unanimously by that panel.

FDA took no further action, explaining there was some unspecified technical shortcomings, and the FDA would issue its own proposal. It eventually did so in November 1982, then withdrew the proposal about a year later, despite the supporting comments of the American Optometric Association, American Academy of Optomology, and Contact Lens Society, of hundreds of practitioners.

In January 1984, CLMA did file for court review. The court's decision, handed down in July 1985, described FDA's rationale as unsettling, and its rejection of evidence somewhat numbing. Unfortunately, the court concluded legally, it could not reverse FDA's decision.

The court stated, we are cognizant of the ironies affected by the statute; many of CLMA's claims are better addressed in Congress. That is the reason we came to Congress. What we are trying to do, and what we believe this bill will accomplish, is to help correct some of those ironies affected by the statute.

That is why we are supporting this bill and the ones previous in the last Congress.

Mr. WHITTAKER. Thank you, Mr. Chairman.

Mr. WAXMAN. Mr. Nielson.

Mr. NIELSON. Thank you, Mr. Chairman.

Mr. Britain, you talked about international competitiveness. Would you like to indicate what moving from section 510(k) to more new applications would be? In other words, what would that do to competitiveness in the industry, in general?

Mr. BRITAIN. Sir, what I was referring to was a focus in FDA, which could make more efficient the movement of medical devices internationally. For example, GMP is a common threat, or let me say quality assurance is a common threat from country to country. It would ease and increase the speed of international trade if there would be a mutual recognition of one GMP in all of the countries.

Not only that, resources would be saved. Instead of manufacturing, Germany having six inspections by six different inspection agencies from six different countries, we would have one. And this is what I meant by something to encourage international competitiveness.

Mr. NIELSON. I may have misunderstood what you said. Let me ask Mr. Magazine. You talk about the section 510(k) as best for the vast majority of medical devices because most of them are done in an incremental basis.

What percentage of the products would be, of that time, they are simply improvements in a model that is already on the market?

Mr. ALLEN. Well, in a recent year, 75 percent of the submissions under the section 510(k) process were for products that were already on the market.

Mr. NIELSON. Of those 75 percent, what would be the impact if we made all of them go through the PMA process and cut section 510(k), as is this legislation's request? How much additional cost in terms of testing on the manufacturer and FDA as well would be involved?

Mr. ALLEN. I think it would bring FDA to a standstill. They just would not be capable of processing all of those products if they could not rely on substantial equivalence provision.

The amount of cost to the manufacturers would increase exponentially. If a manufacturer has a choice of going the PMA route and the section 510(k) route, they would choose the section 510(k).

Mr. NIELSON. Any of you can answer this. Do you find FDA is increasingly moving toward PMA route rather than section 510(k)?

Mr. ALLEN. They are increasingly requesting data comparable to that required under the PMA process. The approval process that FDA, can best be described as a spectrum, rather than two distinct boxes, one being section 510(k) and one being PMA; the data requirements under section 510(k) are increasing and are beginning to merge with those for PMA products.

Mr. MAGAZINE. Congressman, if I may, I indicated I am new to the industry, and I have been spending a good deal of time moving around meeting our members around the country. That is the one issue I am hearing most. More and more data, more and more request for information being kicked back as part of the section 510(k) process, delaying approvals.

If I may, just as a followup to address your question to Mr. Britain, if we have learned anything from the Japanese, it is that the big breakthroughs don't win the day. American manufacturing is learning incremental improvement is the key to international competition, being able to come up with new products, improved products, and so on.

Phasing out the section 510(k) process, requiring more data going through PMA type process can only hurt American manufacturers in competition worldwide.

Mr. NIELSON. You made a couple of comments in your statement, Mr. Magazine. I apologize. I only had time to hear Mr. Britain, but the only one I have had time to read is yours, Mr. Magazine. That is why I am concentrating on you and Mr. Britain.

First of all, you said definition of safety is unduly narrow, and I would like to know how you would broaden the definition of safety? You kind of wave at it, but you don't say.

Mr. MAGAZINE. I think what we are trying to—the information we are trying to put forward, or the position we are trying to put forward is that by getting products on the market, that certainly

accrues to the benefit of the American people and the patients around the country.

It is a slightly skewed definition of safety, perhaps, but these products are needed by the American public, and my going through a section 510(k) process——

Mr. NIELSON. Greater good for greater number is more important than individual safety?

Mr. MAGAZINE. No, sir.

Mr. NIELSON. May I follow, Mr. Chairman?

Mr. WAXMAN. Yes.

Mr. NIELSON. Hopefully a better question. You say that we have not made a case that FDA needs more people and until FDA makes that case, there is no reason to give them extra people, FDA is not requesting them, and you spend a little bit of time on that.

There is no real assurance they need additional authority or additional personnel. Were you not persuaded by the remarks this morning, the IG and GAO, they do need more people, they are not doing the job?

Mr. ALLEN. We did not mean to leave the impression we thought there were not enough people at FDA. We simply requested the committee to look at the authority that currently exists at FDA and to determine whether new authority is necessary, and if that is the case, to assure that there are resources at FDA for those new authorities to be carried out.

I don't think—we did not mean to leave the impression there were plenty of people at FDA. I think there is universal belief here they are very strapped.

Mr. NIELSON. I have another question I would like to submit for the record.

Mr. WAXMAN. Thank you, Mr. Nielson.

Gentlemen, other members as well as Mr. Nielson may have further questions that we would like you to respond to in writing for the record, and we would appreciate it if you would do that.

Thank you for your testimony. We look forward to working with you on this legislation. That concludes the hearing for today. We stand adjourned.

[Whereupon, at 2:50 p.m., the subcommittee was adjourned.]

[The following statements were submitted for the record:]

34-954 0 - 90 - 9

AMERICAN SOCIETY OF
PLASTIC AND RECONSTRUCTIVE
SURGEONS, INC.

Mr. Chairman, the American Society of Plastic and Reconstructive Surgeons (ASPRS) appreciates the opportunity to present testimony to your Subcommittee on H.R. 3095, "The Safe Medical Devices Act." ASPRS is comprised of approximately 4000 members, a number which represents 97% of all plastic surgeons certified by the American Board of Plastic Surgery.

This legislation establishes reporting and tracking requirements for Class III devices. Class III includes a wide array of active and passive devices ranging from heart valves to contact lenses. Active devices are necessary for sustaining life and others that are passive simply assist the human body to function in less critical ways. We are particularly interested in this legislation because breast implants are passive medical devices included under the Class III heading. In June, the American Medical Association (AMA) addressed the issue of a registry of implantable devices and considered the distinction between active and passive devices. ASPRS subscribes to the AMA position which focuses on tracking of "long-term implanted devices that pose a significant risk of serious harm or death to patients if they malfunction or fail completely." (Report of the Board of Trustees:JJ(A-90)).

As physicians, we are fully committed to assuring the safety and effectiveness of medical devices. However, we are concerned that the reporting and tracking requirements called for in this legislation place an impossible burden on the physician.

Specifically, we are concerned with the following language: "Sellers must obtain records to insure that patients can be provided notification." The word "seller" would obviously

include manufacturers, distributors, and hospitals. However, in many cases the physician is the seller and may be indirectly caught up in the maintenance of these records. To rely on the physicians to fulfill a tracking requirement would be very difficult due to the burdensome paperwork and expenses involved, as well as the possibility of the doctor's death, disability, or retirement. Some clarification is needed concerning whether the office based physician seller is indirectly included in this legislation and to what degree.

If the physician seller is included, should there be some form of initial registration process in which the doctor collects all of the necessary information prior to treatment of the patient? How extensive must this information be? Does the responsibility end here, or is the physician expected to collect and accumulate data on his patients for an indefinite number of years?

Another consideration that warrants attention from the Committee is whether the requirement for disclosure of patient information is to be mandatory or voluntary. If it is to be mandatory, it may be necessary to inform each patient of the tracking process prior to surgery, and to include this information when obtaining informed consent.

However, many implant patients will consider a mandatory requirement a violation of their privacy and rights to confidentiality. This is especially the case with breast-implant recipients. These patients are likely to avoid compliance with any follow-up tracking attempts. For example,

they may disregard annual update inquiries. This type of adverse behavior will make a long-term tracking process very difficult.

On the other hand, if the reporting requirement is to be voluntary, it is likely that many patients will choose not to participate. This lack of response will make it virtually impossible to establish a comprehensive tracking process. Obviously, both mandatory and voluntary reporting requirements have their downside. Neither one can guarantee tracking validity. Is the physician to be held accountable for this too?

We are concerned that the use of the word "insure" in the bill's language implies that the record-keeping system must be sufficient to allow location of <u>every</u> patient. This is a staggering thought when you consider the thousands of patients, the frequency with which individuals move, and (especially in regard to breast implants) the number of females who marry and change their last names. In 1988, ASPRS commissioned a study by Dennis Deapen, DrPH, to investigate the merits of a breast-implant monitoring system. As part of the Deapen study, researchers traced 3,000 breast implant patients in Los Angeles County. At the time of their most recent evaluation, only 2,000 of the original 3,000 women were still residing in the county -- and the cost to track those patients was nearly $75,000. Extrapolating this cost to the 130,000 or more patients who receive breast implants annually, plus the estimated 2 million women who already have received breast implants, it would appear that a comprehensive national tracking or registry system could generate unnecessarily high costs. Dr. Deapen's study therefore

concluded that such a system would be "impractical and of a limited value in assessing the most important safety issues."

An initial registration process might be sufficient in the beginning, but without some type of reliable follow-up process it will be impossible to stay informed on the whereabouts of all device users. And, as previously mentioned, regardless of whether such a follow-up tracking mechanism is mandatory or voluntary, it will inevitably be incomplete and insufficient for locating every patient.

This raises the issue of physician accountability. If the physician is to be held responsible, without any consideration of the difficulties associated with a tracking requirement, then physicians are likely to become targets of HHS enforcement and to be subject to civil penalties based on their inability to locate all of their patients.

We believe the language needs to be modified to allow for the physicians' inability to locate the patients. More importantly, the legislation needs to more precisely state the obligations of the physician in regard to tracking patients.

ASPRS recognizes that the intent of this legislation is ultimately to protect the patient, who as a recipient of a Class III medical device deserves the assurance that it is safe and effective. However, we are concerned that in striving to achieve this worthwhile goal, the legislation places an impossible burden on the physician.

Again, ASPRS appreciates the courtesy of the Committee in considering its views.

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TESTIMONY OF COMDISCO MEDICAL LEASING GROUP, INC.

BEFORE THE SUBCOMMITTEE ON
HEALTH AND THE ENVIRONMENT

JULY 26, 1990

PERTAINING TO H.R. 3095

Mr. Chairman and Members of the Committee, Comdisco Medical Leasing Group, Inc. is pleased to be able to submit written testimony pertaining to H.R. 3095, the Safe Medical Devices Act of 1990.

By way of background, Comdisco Medical Leasing Group ("Comdisco") is a wholly owned subsidiary of Comdisco,Inc., one of the nation's largest equipment leasing companies. Comdisco is headquartered in Rosemont, Illinois which is just outside of Chicago.

Comdisco's interest in H.R. 3095 is narrowly focused. As a company which is engaged in the remarketing of previously used medical equipment, we are concerned about those provisions in the legislation which would require "remanufacturers" of medical devices to comply with all of provisions of sections 510 and 515 of the Food, Drug and Cosmetic Act.

The growing market for leased medical equipment and for used medical equipment emanates from changes in federal reimbursement policy that have occurred since the early 1980s. Previously, the economic incentives available as "pass-throughs" of capital costs were so highly favorable that even financially strapped hospitals found it preferable to buy equipment, even very expensive diagnostic and therapeutic devices.

A different environment has been created by the advent of the Medicare Prospective Payment System and Diagnostic Related Groups in 1983, changes in treatment of capital costs, overall cost containment pressures, and a sharp increase in the financial and market competition among hospitals. Now, for financial management reasons, a desire to avoid technological obsolescence, or the desire to expand capacity and capture market share, many hospitals are willing to consider leasing (rather than owning equipment) and are interested specifically in purchasing or leasing used medical equipment that has been restored or reconditioned in a high quality manner.

The 1988 House-passed bill, as well as the current H.R. 3095, contain a provision which would require "remanufacturers" to comply with all of section 510 and defines remanufacturing to include "fabrication, assembly, substantial alteration, processing, or reprocessing or a device which has been previously introduced into interstate commerce" if such activities are not "part of routine service on the device."

This language could be interpreted as encompassing the remarketing business and therefore a considerable change from its current regulatory status. There is probably good sense in having companies engaged in the medical device remarketing to comply with many of the FDC Act's requirements, such as the registration and listing requirements of section 510. However, it is not appropriate to have remarketers covered by section 510(k) and the Act's pre-market application (PMAs) requirements, as if a new medical device was being created.

Specifically, there are three objections to remarketers being covered by section 510(k) and the PMA provisions:

- The remarketing process does not, in fact, create a new medical device. The equipment, after being restored and reconditioned, does not vary from its original structure or intended use. In fact, any defective or worn components are replaced with new components that are identical to those that would be supplied by the manufacturer in the course of maintaining or upgrading the equipment, such that the equipment will perform to the manufacturer's specifications. Thus, it is without purpose to make remarketers go through the requirements of 510(k) and PMA, which are specifically designed for new medical devices.

- In order to file a 510(k) or PMA for remarketed equipment, a remarketer would need access to proprietary information of the manufacturer contained in the original 510(k) or PMA. Needless to say, no manufacturer is going to provide a remarketer with this information. This leads to an impossible compliance situation.

- Even if all of the information needed to comply with 510(k) and PMA filing requirements were available, the expense and delay to a remarketer would add substantially to the sale price of the remarketed equipment, without adding any increment of safety or value. Expense and delay would be associated with both the preparation of the filings by the remarketer and time waiting for approval by FDA. In addition, such filings would add to FDA's review burden without any gain to the agency or the public.

The bottom line is that remarketers will probably not be able to stay in the business if a 510(k) or PMA was required, both because of impossibility of compliance and expense. Not only would it be unfortunate for a legitimate industry to be regulated out of existence, but this would undercut the remanufacturing industry's very real potential to contribute to health care cost containment. This contribution takes two forms:

- In a significant number of situations, remarketed equipment represents a cost effective alternative to new equipment for a health care provider; and

- This equipment provides competition for the original manufacturer who must provide better performance or true innovation to differentiate his new products when they are introduced.

Attached to this testimony for the Committee's consideration is legislative language which specifically addresses our concerns. We respectfully request that the Committee consider our suggested language when it moves to mark up this important legislation.

Again, thank you for the opportunity to express our views on H.R. 3095.

DRAFT LEGISLATIVE LANGUAGE

1. Insert at the beginning of paragraph (3): "except as provided in paragraph 4".

2. Add new paragraph 4:

" (4) the term 'manufacturer' does not include a person that reintroduces, or arranges for the reintroduction, into interstate commerce of, or engages in or arranges for the reconditioning or restoration (which may involve the addition, removal, substitution or replacement of a component or components) of, a device (other than a device intended for implantable use in humans to support or sustain life) that (A) was previously lawfully introduced into interstate commerce, and as so reintroduced, reconditioned, and/or restored (B) has the same intended use as set forth in the manufacturer's original or superseding labeling as applicable, and (C) has not been substantially altered from the manufacturer's original or superseding specifications as applicable.

3. Add to section 510 a new subsection at the end thereof:

"(l) A person described in subsection (a) (4) of this section and any devices reconditioned, restored, or reintroduced into interstate commerce by such person as described in subsection (a) (4) shall not be subject to the requirements of subsection (k) of this section or to section 515 or section 501(f) of this Act. Such person and such devices shall be subject to all other otherwise applicable provisions of this Act.

Section __ of the bill exempts from the pre-marketing review and approval provisions of the statute (§§ 510(k), 515, and 501(f)) reconditioners and restorers of medical devices and reconditioned or restored devices. The exemption applies only where a device was previously lawfully introduced into interstate commerce and, as reintroduced, has the same intended use as set forth in the manufacturer's original or superseding labeling as applicable, and has not been substantially altered from the manufacturer's original or superseding specifications as applicable. Reconditioners and restorers as well as the devices they recondition or restore will be subject to all other applicable provisions of the statute-- including registration and listing, the prohibitions of adulteration and misbranding, medical device reporting, good manufacturing practice requirements, otherwise applicable performance standards, and all the remedies otherwise applicable.

Devices that have been reconditioned or restored are excluded from the requirements of §§ 510(k) and 515 because the process of reconditioning or restoration does not create a new device-- either as to intended use or as to performance specifications. Consequently, FDA review of the safety and effectiveness of such devices would be unnecessary and wasteful -- for the agency, for reconditioners and restorers, and for their customers (hospitals and other health care providers). Moreover, reconditioners and restorers generally do not have access to the original manufacturer's proprietary data, which may be necessary for FDA review of safety and effectiveness. Because a healthy market in reconditioned and restored medical devices can help significantly to reduce medical costs without compromise in quality of care, it is in the public interest to refine regulatory requirements so as to enable that market to develop.

CONTACT LENS ASSOCIATION OF OPHTHALMOLOGISTS

The Contact Lens Association of Ophthalmologists, a medical subspecialty society representing over 2,200 ophthalmologists nationwide engaged in the research, development and fitting of contact lenses, appreciates the opportunity to share with you some of our thoughts on medical device reform.

OVERVIEW

CLAO has long had an interest in the safety aspects of contact lenses. In fact this is what prompted the founding of CLAO*. The history of this may be of interest to this Committee. It is a tried, but true saying that those who do not know history are doomed to repeat it. Corneal contact lenses, i.e., hard gas-permeable lenses, were first developed by an optician, Kevin Tuohy, in 1948. During the early 1950's the use of corneal lenses became widespread. There was no governmental

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* On March 28, 1969, CLAO was incorporated as a non-profit organization in Albany, New York. Its objectives cited in the certification of incorporation, were as follows:

1. To encourage, stimulate and assist its members, all of whom shall be duly licensed physicians engaged in the medical specialty of ophthalmology, to engage in research with respect to fitting and prescribing of contact lenses and ophthalmological problems attendant thereto.
2. To provide channels for the exchange and dissemination of knowledge among its members and other members of the medical profession with respect to ophthalmological problems involved in the prescribing and fitting of contact lenses and the medical management of such patients.
3. To encourage physicians, medical students, medical technicians, and members of medical schools and hospitals to interest themselves in research and reporting with respect to the ophthalmological problems involved in the fitting and prescribing of contact lenses by granting awards, scholarships, and other assistance.

regulation of contact lenses, nor their accessory care solutions. There existed the perception that contact lenses were innocuous devices that could be fabricated by any laboratory without having to conform to any type of performance standards. Suffice it to say, the quality of these lenses varied considerably. Similarly contact lens care solutions and storage cases were also unrequlated with comparable variation in quality. Eventually, as might be anticipated, complications arose. In 1962, Allen and Dixon reported eye infections due to contact lenses being stored in contaminated solutions. In fact, the solutions were often the source of contamination. This became such a serious problem that some questioned whether lenses should be stored in solutions. Further studies established the fact that wet storage resulted in a more comfortable lens. The real problems were that the preservatives in the solutions were not of adequate concentration, and that the storage cases were faulty in design. In 1966, Dixon et al. reported 14 eyes with loss of vision due to contact lenses. It was obvious that standards needed to be established. This concern led to the founding of CLAO.

Soon thereafter, CLAO and other interested groups, encouraged the American National Standards Institute (ANSI) to formulate standards for contact lenses. These were the consensus standards developed by ophthalmology, optometry, opticinary and industry.

In 1970, a new development occurred. This was the introduction of soft lenses. This time the FDA acted. They declared these devices to be "drugs", and so regulated them. In retrospect, despite all of the initial criticism by fitters and industry, now all agree that this was the best

thing that could have happened. The original lenses were of poor quality, and fraught with danger to the patients. What eventually emerged, after the lenses had satisfied the FDA pre-market approval, was a vastly superior soft lens from both the standpoint of scientific quality and patient safety. Both the ophthalmic profession and industry owe a debt to the FDA.

The next development, the Medical Device Amendment of 1976, seemed to be a logical step. Contact lenses and their solutions, would now be regulated as medical devices according to a three-tiered classification format. Initially, contact lenses (since they were pre-amendment medical devices) would be designated as "transitional devices" and so relegated to Class III. However, after the material was proven to be safe and effective, it could then move into Class II wherein the lenses would still need to meet performance standards. Finally, if a material proved to be innocuous over a prolonged period of time, it could then be assigned to Class I wherein the manufacturer's primary obligation would be to conform to a good manufacturing process (GMP). All of this seemed to be sensible. In practice, some lenses (e.g., PMMA lenses) and most solutions are simply "grandfathered in" as Class I. This is by custom, not law.

EVALUATION OF THE MEDICAL DEVICE AMENDMENTS

We would like to praise the House position on transitional devices. H.R. 3095, like its predecessor, H.R. 4640, calls upon the FDA to examine over three years the status of transitional devices, <u>without</u> the threat of a sunset or automatic reclassification.

In contrast, the Senate Labor and Human Resources Committee has

historically focused on one transitional device -- contact lenses -- and mandated that one medical device would be automatically reclassified if the FDA failed to act by the end of one year. Given the FDA's workload, it is clear that a review would not be completed for several years. Thus, this legislation would force the reclassification of contact lenses which the FDA in a formal proceeding had refused to reclassify due to their inability to assure safety and effectiveness without pre-market testing.

Automatic reclassification would not be in the best interest of our patients, as patients might obtain untested lenses of poor quality.

The state of the art is not such that these RGP lenses can be moved into Class I without patient risk. Remember the experience in the 1950's. Laboratories who are not required to meet performance standards may manufacture lenses of poor quality. Performance standards are needed to guarantee patient safety. With this concern in mind, CLAO urges opposition to any legislatively mandated reclassification scheme which could result in reclassification without performance standards being securely in place.

PERFORMANCE STANDARDS AND STREAMLINING

One might ask, "Why has the FDA not written performance standards?" There is no simple answer. Several years ago the FDA attempted to simplify the PMA for Class III. The results was a ninety page document that was as restrictive as the original. The FDA, in its role as the protector of the public, has to consider every possibility no matter how remote.

While performance standards would be in place in an ideal world, the

FDA has succeeded in greatly reducing the burden of regulation in the real world by their streamlining proposals. The FDA's efforts over the year, in aggressively streamlining the regulatory process, have significantly reduced requirements -- especially for small manufacturers -- without imperiling the public safety.

CIAO agrees with the FDA that the public and our patients are best served by continuing to streamline the regulatory process, rather than face the risks to the public entailed in a mandated reclassification.

SUMMARIZATION OF CIAO'S POSITION

The existing FDA classification process is in the best interest of patient safety, but has not functioned well in that most contact lenses have remained in Class III.

There are no performance standards so it is technically impossible to move substantially equivalent lenses that have already proven to be safe and effective into Class II.

CIAO opposes legislative proposals to reclassify lenses. Automatic reclassification could threaten the public health by exposing our patients to untested lenses of poor quality.

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STATEMENT OF THE CONTACT LENS INSTITUTE

H.R. 3095

House Committee on Energy and Commerce

Before the Subcommittee on Health and the Environment

July 17, 1990

INTRODUCTION

This statement is submitted on behalf of the Contact Lens Institute (CLI), a not-for-profit organization consisting of research-based manufacturers of soft and rigid gas permeable contact lenses and contact lens accessories and dedicated to promoting the safety and effectiveness of those products. Such products are regulated by the U.S. Food and Drug Administration (FDA) as medical devices under the "Medical Device Amendments of 1976".

CLI expects that the Subcommittee will be receiving diverse views from many organizations. CLI's principal concern in medical device legislation is the issue of "reclassification" from Class III to Class II or Class I of soft and rigid gas permeable contact lenses and contact lens accessories. CLI's statement will focus on that issue.

OVERVIEW

CLI applauds the efforts of the Subcommittee to address in a comprehensive manner its concerns regarding the current scheme of regulation of medical devices. CLI particularly commends the provisions of H.R. 3095 dealing with transitional devices, which call upon the FDA to review the classification of all transitional devices over a three year period. These provisions do not single out any specific medical device or imperil the FDA's authority to regulate by providing for the automatic reclassification of any medical device.

These provisions mirror those found in H.R. 4640, the comprehensive medical device reform legislation which passed the House in 1988. Indeed, H.R. 3095 contains no provision for the automatic reclassification of contact lenses if the FDA fails to complete its review of the appropriateness of their current classification within an arbitrarily established time period.

Over the years the manner in which FDA has regulated soft and rigid gas permeable contact lenses and contact lens accessories has been singled out for special attention by the FDA, the courts, and the Congress to an extraordinary and, CLI believes, inordinate degree. Specifically, certain segments of the contact lens industry have over the years sought

"reclassification" of soft and rigid gas permeable contact lenses and contact lens accessories from Class III to Class II or Class I. As discussed in detail below, CLI opposes such reclassification unless it is founded on an adequate scientific basis and in any case opposes the automatic reclassification of those products if the FDA is unable to review the adequacy of the scientific basis for their current classification within a limited, arbitrarily established period of time.

BACKGROUND

In 1981 the Contact Lens Manufacturers Association (CLMA) -- a group of manufacturers of hard and rigid gas permeable contact lenses -- petitioned FDA to reclassify certain types of contact lenses from Class III, which requires pre-market approval, to Class II, which would effectively subject the devices only to so-called "general controls." Such "general controls" are of the kind which the Federal Food, Drug, and Cosmetic (FDC) Act imposes on common devices such as first-aid bandages and tongue depressors.

Members of CLI -- companies with extensive experience in studying the safety and effectiveness of contact lenses -- opposed such action, believing that "general controls" alone are inadequate to protect the public health and ensure the

availability of contact lenses without unnecessary risks of eye injury or infection from poorly formulated or inadequately tested lenses.

After two extensive regulatory proceedings the FDA rejected the arguments of the proponents of "reclassification" of rigid gas permeable contact lenses. The FDA concluded:

> "Class III is still necessary to provide reasonable assurance of the safety and effectiveness of rigid gas permeable lenses . . . . [A]t this stage in their development, there is no substitute for clinical trials to provide reasonable assurance of the safety and effectiveness of these lenses" (48 Fed. Reg. 56781).

The proponents of reclassification then took the matter to court. The court also rejected their arguments. They have since been importuning Congress -- through automatic reclassification legislation -- to do legislatively what the FDA declined twice to do on the basis of the evidence presented. Like FDA and the judiciary, Congress has rejected their arguments as well.

H.R. 3095 - SUMMARY OF THE POSITION OF THE CONTACT LENS INSTITUTE

The Contact Lens Institute opposes any legislative effort to automatically reclassify soft and rigid gas permeable contact lenses and contact lens accessories from Class III into Class II or Class I without a sound scientific basis for so doing. CLI further believes that the FDA is the proper forum in which to

develop any such scientific basis. As noted, FDA has reviewed that scientific basis -- not once but twice -- and has found it wanting.

CLI's position with respect to the automatic reclassification of soft and rigid gas permeable contact lenses and lens accessories can be summarized as follows:

1. The FDA has Twice Rejected Reclassification of Rigid Gas Permeable Contact Lenses from Class III: In two separate proceedings, the FDA and a panel of medical and scientific experts reviewed the classification of contact lenses and determined that there is no "valid scientific evidence" to support the relaxation of the requirement of pre-market approval. CLI agrees with FDA's findings and determinations.

2. The Safety and Effectiveness of Contact Lenses Cannot be Assured Without the Preclinical and Clinical Testing required for Class III Products: Rigid gas permeable lenses are composed of polymers in which even slight changes in formulation may affect the safety or effectiveness of the lens or its reliability or lens-to-lens variability. The pre-market approval process

ensures that new formulations of contact lenses as well as formulation changes in existing contact lenses are adequately tested before they are marketed to the public. Automatic reclassification of contact lenses without adequate assurance that essential testing will continue to be required raises the possibility that unsafe or ineffective contact lenses will reach the market, thereby jeopardizing the eyesight of the consuming public.

3. Waste of Scarce FDA Resources: The FDA budget is stretched thin already, given the agency's responsibility for assuring the safety of our food, drugs, cosmetics, and other medical devices. Having already reviewed the classification of contact lenses twice, the FDA should not be asked to devote its limited resources to conducting a hasty third review in order to avoid the reclassification of such devices by legislative fiat. This is particularly so in light of the fact that FDA has in recent years significantly streamlined the review process and is currently considering in an orderly fashion proposals from industry to further streamline the process, including administrative reclassification based upon certain assurances as to requirements for essential testing.

4. No Consumer Benefit in Relaxing Regulation of Contact Lenses: Automatic reclassification of soft and rigid gas permeable contact lenses from Class III to Class II or Class I would provide the consumer with no demonstrated and certainly no substantial reduction in the cost of the lenses. By far the largest component of the cost of obtaining a contact lens is the visit to the eye care professional for the initial fitting, which may run as high as several hundred dollars. The wholesale cost of the lens itself, however, may be as low as $2.50. As a result of vigorous competition in the contact lens industry, moreover, that price has decreased considerably over the years.

5. CLI Commitment to Regulatory Streamlining: CLI has made several proposals to the FDA to streamline the regulatory process for approving contact lenses. In 1986 CLI proposed five such measures, three of which the agency has adopted to date. The FDA has, of course, also initiated and implemented constructive streamlining proposals on its own, consistent with ensuring the safety and effectiveness of contact

lenses. These reforms have benefited the government and all manufacturers of contact lenses by speeding up the approval process for certain changes in contact lenses.

FDA testified in 1989 before the Senate Appropriations Committee in favor of streamlining the approval process through administrative modifications rather than through legislatively mandated reclassification. CLI endorses FDA's position.

It has been the long standing position of CLI that significant streamlining of the contact lens approval process is in the public interest so long as proper safeguards of safety and effectiveness are maintained. Over the past several months CLI has been working with FDA and CLMA to develop a regulatory scheme in which even greater streamlining of the process with appropriate safeguards might be achieved. This approach is designed to ensure that necessary testing, including, where appropriate, confirmatory clinical testing, is carried out on all contact lens products before they are marketed. To achieve this result CLI

is looking to the inherent flexibility in the 510(k) process to determine whether necessary testing can be required as a basis for a "substantial equivalence" determination.

If CLI can be assured that the 510(k) process can be used to require essential showings of safety and effectiveness of contact lenses and lens care products, CLI is prepared to support and/or initiate an administrative reclassification of the products. Our initial meetings with FDA and CLMA on this project have been most promising and further meetings are planned.

CLI will continue to urge upon the FDA responsible measures to expedite the review of contact lens applications for approval. Unlike automatic reclassification proposals, however, CLI's recommendations to the agency recognize the need for preclinical and clinical testing as appropriate as a means of continuing the high degree of safety and efficacy associated with contact lenses.

DISCUSSION

The members of the Contact Lens Institute are principally responsible for the current state of the art in the research, development, testing and manufacture of contact lenses and attendant accessories and the delivery of quality products to the public at affordable prices. Millions of Americans now enjoy the safety, convenience and comfort that extensively-tested yet reasonably priced contact lenses provide because of the efforts of the members of the Contact Lens Institute.

The Medical Device Amendments of 1976 make clear the intention of Congress to ensure that the marketing of medical devices is regulated in such a way as to resolve questions regarding safety and effectiveness in favor of the public health. Thus the burden of demonstrating that a product which is currently subject to pre-market approval can properly be regulated as a Class II or Class I device appropriately falls on the proponents of reclassification.

During FDA's deliberations on the two proposals to reclassify contact lenses, the agency provided more than ample opportunity for all affected parties, including the proponents of reclassification, to present evidence in support of their

position. The agency's decision against reclassification demonstrated, in CLI's view, a thoughtful analysis of all publicly available information, including that which was submitted by the proponents of reclassification.

Reclassification would, of course, make it easier for additional manufacturers, including overseas manufacturers, to export their products to the U.S. Balance of trade considerations aside, reclassification without adequate safeguards would eliminate FDA's ability to scrutinize such lenses and to determine whether the processes involved in their manufacture are adequate to assure that the composition, quality, and safety of the lenses match those of U.S. manufacturers.

CONCLUSION

The Contact Lens Institute opposes any legislative initiative to automatically reclassify soft and rigid gas permeable contact lenses or lens accessories -- products which are currently classified as Class III -- into Class II or Class I without a sound scientific basis for so doing. CLI further believes that the FDA is the proper forum in which to develop any such scientific basis. Contact lenses are not harmless or innocuous medical devices. They are not bandages or tongue depressors.

The human eye is a delicate and complex organ. Sight is too precious to be weighed lightly against the promise of a decrease in cost which is speculative at best and which would be small by any measure. The Medical Device Amendments of 1976 rightly demand solid proof of reasonable assurance of safety and effectiveness prior to reclassification of a medical device. The Food and Drug Administration has faithfully implemented the law by its previous decisions on contact lenses.

The Contact Lens Institute intends to continue providing assistance to the FDA to develop ways to streamline the administrative process of approving contact lenses and contact lens accessories and thereby to reduce costs to consumers in ways which are consistent with maintaining the safety, effectiveness, and high level of quality of these products.

CLI commends the Subcommittee's efforts to assure that the FDA has the authority and resources necessary to appropriately and effectively regulate medical devices generally and contact lenses in particular.

STATEMENT OF POSITION
H.R. 3095

SUMMARY STATEMENT

Osbon Medical Systems, Ltd.
Augusta, Georgia

MR. CHAIRMAN: Concerns about the "substantial equivalence" provision of the FDA's 510(k) (permission to market) process are increasing rapidly in my field of external vacuum therapy for the treatment of erectile dysfunction.

The FDA's vaguely written letter granting permission to market and their lack of tools and staff to adequately enforce compliance are causing ethical manufacturers like Osbon Medical Systems to become seriously concerned about the possibility of misinformation, misuse, abuse and therefore injury among some users of external vacuum devices. We are also concerned that most of the consumer population for these products is over the age of 60 -- an especially vulnerable audience.

Let me be specific. All 510(k) permissions granted in this field reference a "prescription only" external vacuum device. The FDA assures us that any device subsequently marketed under "substantial equivalence" must require a prescription to be in compliance.

Yet we have direct experience of at least six such devices that are available by mail without prescription, a situation which eliminates the physician's involvement, eliminates a medical assessment of a patient's total condition and precludes professional instructions for use.

Since erectile dysfunction is a secondary disorder, most physicians we know consider a complete medical examination to be an essential part of its treatment. We all know that self-diagnosis and self-treatment of any condition, by mail or over the counter, creates a classic climate for injury and also precludes discovery and treatment of pre-existing conditions -- some of which could be life-threatening.

As the developer of external vacuum and constriction therapy for impotence management, my Company feels a personal obligation for its safe use. We therefore employ a method of delivery which includes education and support to enhance safe use for every owner. We are concerned that small companies like ours who adhere to and often exceed federal safety

regulations may be seriously harmed if the FDA is unable to monitor the kind of abuse I have cited, the kind of abuse tacitly encouraged by the present 510(k) process.

The current method grants marketing permission on the basis of a written declaration of equivalence alone. There is no requirement to test or submit a prototype; "equivalence" is loosely based on physical similarity alone. This policy allows less scrupulous companies to bring products into the market without being actually handled or viewed by the FDA (other than by sketch or photo), and therefore, with only paper documentation of product specifications. "Substantial equivalence" is open to various interpretations on both sides.

The 510(k) process as presently written and enforced is allowing entries into the industry which ignore the very types of equivalence (such as prescription requirement, method of delivery and actual physical comparison of materials) which probably account for the exceptional record of safety and effectiveness in the reference product.

If injury begins to occur among users of external vacuum devices because of the perceived lax regulatory climate of the present 510(k) process, we fear that any resulting legislation or enforcement would be severely restrictive and equally applied to all manufacturers, regardless of their prior record of ethics, safety, effectiveness or clinical support. Thus, a few unscrupulous "loophole" manufacturers could irreparably harm solid, legitimate, ethical companies and could thereby deprive a large segment of the population of a safe and economical treatment option.

I ask the subcommittee to protect consumers and ethical small manufacturers from the adverse situation created by the present 510(k) "substantial equivalence" provision by considering the following recommendations:

1) that the 510(k) process be strengthened to require actual prototype comparison and testing of product specifications to the reference product;

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2) that the 510(k) process be strengthened to require of applicant products a method of delivery comparable to the reference product;

3) that the 510(k) process be strengthened to require proof of adequate liability insurance among manufacturers of all classes of medical devices;

4) that the 510(k) process be strengthened to safeguard the consumer from both the advertising and availability of "sexual enhancement products" over the counter, including Class I devices, in line with the January, 1990 ban of aphrodisiac products;

5) that the 510(k) process be strengthened to provide some means of civil recourse for manufacturers or others who are willing to monitor and report violations of FDA product safety regulations.

Thank you for your attention. I appreciate this oportunity to speak before you.

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